

UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549

FORM 10-Q

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

FOR THE QUARTERLY PERIOD ENDED SEPTEMBER 30, 2024  
OR

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

FOR THE TRANSITION PERIOD FROM \_\_\_\_ TO \_\_\_\_.

Commission file number 001-38356

VYNE THERAPEUTICS INC.

(Exact name of registrant as specified in its charter)

Delaware

45-3757789

(State or other jurisdiction of  
incorporation or organization)

(I.R.S. Employer  
Identification No.)

685 Route 202/206 N, Suite 301  
Bridgewater, New Jersey 08807

(Address of principal executive offices including zip code)

(800) 775-7936

(Registrant's telephone number, including area code)

(Former name, former address and former fiscal year, if changed since last report)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value \$0.0001	VYNE	The Nasdaq Stock Market LLC

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes  No

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files).

Yes  No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act:

Large accelerated filer	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input checked="" type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
		Emerging growth company	<input type="checkbox"/>

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).

Yes  No

As of November 1, 2024, there were 14,751,433 shares of the registrant's Common Stock, par value \$0.0001 per share, outstanding.

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#### **SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS**

This Quarterly Report on Form 10-Q contains "forward-looking statements" within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). All statements other than statements of historical facts contained in this Quarterly Report on Form 10-Q are statements that could be deemed forward-looking statements reflecting the current beliefs and expectations of management with respect to future events or to our future financial performance and involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by these forward-looking statements. These statements are often identified by the use of words such as "aim," "anticipate," "assume," "believe," "contemplate," "continue," "could," "due," "estimate," "expect," "goal," "if," "intend," "may," "objective," "plan," "predict," "potential," "positioned," "seek," "should," "target," "until," "will," "would," and similar expressions or variations.

These forward-looking statements include, but are not limited to, statements regarding the following matters:

- our ability to successfully execute our business strategy, including our ability to successfully develop our bromodomain and extra-terminal domain ("BET") inhibitor platform for immuno-inflammatory conditions;
- the timing of commencement of future preclinical studies and clinical trials and timing of data from those studies and trials;
- our ability to enroll patients and successfully complete, and receive favorable results from, clinical trials of our product candidates;
- regulatory requirements or developments, and our ability to obtain necessary approvals from the U.S. Food and Drug Administration (the "FDA") or other regulatory authorities for our product candidates;
- our pursuit of, and ability to successfully identify and execute, strategic transactions;
- estimates of our expenses, capital requirements, our needs for additional financing and our ability to obtain additional capital on acceptable terms or at all;
- the potential market size of treatments for any diseases and market adoption of our products, if approved or cleared for commercial use, by physicians and patients;
- disruptions related to macroeconomic conditions on our ability to initiate and retain patients in our clinical trials and progress preclinical studies and the ability of our suppliers to manufacture and provide materials for our product candidates;
- legislative, regulatory, political and geopolitical developments beyond our control, including inflationary pressures, general economic slowdown or a recession, high interest rates, changes in monetary policy, instability in financial institutions, the ongoing conflict in Ukraine, conflict in the Middle East, rising tensions between China and Taiwan and the potential impact of the proposed BIOSECURE Act;
- our ability to create or in-license intellectual property and the scope of protection we are able to establish and maintain for intellectual property rights covering our product candidates and programs, including the projected terms of patent protection;
- developments and projections relating to our competitors and the markets in which we compete, including competing drugs and therapies, particularly if we are unable to receive exclusivity;
- our ability to comply with various regulations applicable to our business;
- our ability to successfully challenge intellectual property claimed by others;
- our intentions and our ability to establish collaborations or obtain additional funding;
- our ability to attract and retain key scientific or management personnel;

- our defense of any future litigation that may be initiated against us;
- our expectations regarding licensing, business transactions and strategic operations; and
- our future financial performance and liquidity.

We caution you that the foregoing list may not contain all of the forward-looking statements made in this Quarterly Report on Form 10-Q. Forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. We discuss these risks in greater detail in "Risk Factors" and elsewhere in this Quarterly Report and in our most recent Annual Report on Form 10-K, as well as in our other filings made with the Securities and Exchange Commission ("SEC") from time to time. Given these uncertainties, you should not place undue reliance on these forward-looking statements. Also, forward-looking statements represent our management's beliefs and assumptions only as of the date of this Quarterly Report on Form 10-Q. Except as required by law, we assume no obligation to update these forward-looking statements, or to update the reasons actual results could differ materially from those anticipated in these forward-looking statements, even if new information becomes available in the future.

#### **COMPANY REFERENCES**

Throughout this Quarterly Report on Form 10-Q, "VYNE," the "Company," "we," "us" and "our" refer to VYNE Therapeutics Inc. and its subsidiaries.

#### **TRADEMARKS**

The trademarks and registered trademarks of VYNE Therapeutics Inc. and our subsidiaries referred to in this Quarterly Report on Form 10-Q include VYNE Therapeutics, InhiBET, our logo and our name and logo used together. Third-party products and company names mentioned herein may be the trademarks of their respective owners.

**PART I – FINANCIAL INFORMATION**

**Item 1. Unaudited Condensed Consolidated Financial Statements.**

**VYNE THERAPEUTICS INC.**  
**CONDENSED CONSOLIDATED BALANCE SHEETS**  
(U.S. dollars in thousands, except share and per share data)  
(Uunaudited)

	<b>September 30,</b>	<b>December 31,</b>
	<b>2024</b>	<b>2023</b>
<b>Assets</b>		
<b>Current Assets:</b>		
Cash and cash equivalents	\$ 16,272	\$ 30,620
Restricted cash	47	54
Investment in marketable securities	53,913	62,633
Prepaid and other current assets	3,303	2,656
<b>Total Current Assets</b>	<b>73,535</b>	<b>95,963</b>
<b>Non-current Assets:</b>		
Operating lease right-of-use assets	122	207
Non-current prepaid expenses and other assets	2,541	1,515
<b>Total Non-current Assets</b>	<b>2,663</b>	<b>1,722</b>
<b>Total Assets</b>	<b>\$ 76,198</b>	<b>\$ 97,685</b>
<b>Liabilities and Stockholders' Equity</b>		
<b>Current Liabilities:</b>		
Trade payables	\$ 3,986	\$ 1,659
Accrued expenses	6,168	4,119
Employee related obligations	1,071	1,645
Operating lease liabilities	123	115
Other current liabilities	1,313	—
<b>Total Current Liabilities</b>	<b>12,661</b>	<b>7,538</b>
<b>Long-term Liabilities:</b>		
Non-current operating lease liabilities	—	99
Other liabilities	—	1,313
<b>Total Long-term Liabilities</b>	<b>—</b>	<b>1,412</b>
<b>Total Liabilities</b>	<b>12,661</b>	<b>8,950</b>
<b>Commitments and Contingencies</b>		
<b>Stockholders' Equity:</b>		
Preferred stock: \$0.0001 par value; 20,000,000 shares authorized at September 30, 2024 and December 31, 2023; no shares issued and outstanding at September 30, 2024 and December 31, 2023	—	—
Common stock: \$0.0001 par value; 150,000,000 shares authorized at September 30, 2024 and December 31, 2023; 14,751,433 and 14,098,888 shares issued and outstanding at September 30, 2024 and December 31, 2023, respectively	1	1
Additional paid-in capital	782,650	780,044
Accumulated other comprehensive income	34	26
Accumulated deficit	(719,148)	(691,336)
<b>Total Stockholders' Equity</b>	<b>63,537</b>	<b>88,735</b>
<b>Total Liabilities and Stockholders' Equity</b>	<b>\$ 76,198</b>	<b>\$ 97,685</b>

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

**VYNE THERAPEUTICS INC.**  
**CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS**  
(U.S. dollars in thousands, except per share data)  
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
<b>Revenues</b>				
Royalty revenues	\$ 121	\$ 114	\$ 417	\$ 348
<b>Total revenues</b>	<u>121</u>	<u>114</u>	<u>417</u>	<u>348</u>
<b>Operating expenses:</b>				
Research and development	10,248	3,318	21,262	13,284
General and administrative	2,964	3,030	10,022	9,490
<b>Total operating expenses</b>	<u>13,212</u>	<u>6,348</u>	<u>31,284</u>	<u>22,774</u>
<b>Operating loss</b>	<u>(13,091)</u>	<u>(6,234)</u>	<u>(30,867)</u>	<u>(22,426)</u>
Other income, net	934	163	3,074	706
<b>Loss from continuing operations before income taxes</b>	<u>(12,157)</u>	<u>(6,071)</u>	<u>(27,793)</u>	<u>(21,720)</u>
Income tax expense	—	—	—	—
<b>Loss from continuing operations</b>	<u>(12,157)</u>	<u>(6,071)</u>	<u>(27,793)</u>	<u>(21,720)</u>
Loss from discontinued operations, net of income taxes	—	(513)	(19)	(544)
<b>Net loss</b>	<u>\$ (12,157)</u>	<u>\$ (6,584)</u>	<u>\$ (27,812)</u>	<u>\$ (22,264)</u>
<b>Loss per share from continuing operations, basic and diluted</b>	<u>\$ (0.29)</u>	<u>\$ (1.85)</u>	<u>\$ (0.65)</u>	<u>\$ (6.66)</u>
<b>Income (loss) per share from discontinued operations, basic and diluted</b>	<u>\$ 0.00</u>	<u>\$ (0.16)</u>	<u>\$ 0.00</u>	<u>\$ (0.17)</u>
<b>Loss per share, basic and diluted</b>	<u>\$ (0.29)</u>	<u>\$ (2.01)</u>	<u>\$ (0.65)</u>	<u>\$ (6.82)</u>
<b>Weighted average shares outstanding - basic and diluted</b>	<u>42,587</u>	<u>3,282</u>	<u>42,592</u>	<u>3,271</u>
<b>Other comprehensive income:</b>				
Unrealized gains on marketable securities, net of tax of \$0	92	—	8	—
<b>Total other comprehensive income</b>	<u>92</u>	<u>—</u>	<u>8</u>	<u>—</u>
<b>Comprehensive loss</b>	<u>\$ (12,065)</u>	<u>\$ (6,584)</u>	<u>\$ (27,804)</u>	<u>\$ (22,264)</u>

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

**VYNE THERAPEUTICS INC.**

CONDENSED CONSOLIDATED STATEMENTS OF CHANGES IN MEZZANINE EQUITY AND STOCKHOLDERS' EQUITY

(U.S. dollars in thousands, except share data)

(Unaudited)

	Mezzanine Equity (Convertible Preferred Stock)		Common stock		Additional paid-in capital	Accumulated other comprehensive income	Accumulated deficit	Total Stockholders' Equity
	Number of shares	Amount	Number of Shares	Amount	Amount			
<b>BALANCE AT JANUARY</b>								
<b>1, 2023</b>	3,000	\$ 211	3,229,704	\$ —	\$ 693,937	\$ —	\$ (662,735)	\$ 31,202
<b>CHANGES DURING THE PERIOD:</b>								
Net loss	—	—	—	—	—	—	(22,264)	(22,264)
Vesting of restricted stock units, net of withholding for tax and shares issued under employee stock purchase plan	—	—	40,488	—	(35)	—	—	(35)
Stock-based compensation	—	—	—	—	2,595	—	—	2,595
Redemption of convertible preferred stock	(3,000)	(211)	—	—	—	—	(149)	(149)
Issuance of common stock in at-the-market offering, net of \$5 in issuance costs	—	—	34,589	—	156	—	—	156
<b>BALANCE AT</b>								
<b>SEPTEMBER 30, 2023</b>	—	\$ —	3,304,781	\$ —	\$ 696,653	\$ —	\$ (685,148)	\$ 11,505
<b>BALANCE AT JANUARY</b>								
<b>1, 2024</b>	—	\$ —	14,098,888	\$ 1	\$ 780,044	\$ 26	\$ (691,336)	\$ 88,735
<b>CHANGES DURING THE PERIOD:</b>								
Net loss	—	—	—	—	—	—	(27,812)	(27,812)
Vesting of restricted stock units, net of withholding for tax and shares issued under employee stock purchase plan	—	—	12,722	—	2	—	—	2
Stock-based compensation	—	—	—	—	2,604	—	—	2,604
Cashless exercise of pre-funded warrants	—	—	639,823	—	—	—	—	—
Unrealized gains from marketable securities	—	—	—	—	—	8	—	8
<b>BALANCE AT</b>								
<b>SEPTEMBER 30, 2024</b>	—	\$ —	14,751,433	\$ 1	\$ 782,650	\$ 34	\$ (719,148)	\$ 63,537

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

**VYNE THERAPEUTICS INC.**  
**CONDENSED CONSOLIDATED STATEMENTS OF CHANGES IN MEZZANINE EQUITY AND STOCKHOLDERS' EQUITY**  
(U.S. dollars in thousands, except share data)  
(Unaudited)

Mezzanine Equity (Convertible Preferred Stock)	Accumulated						Total Stockholders' Equity
	Common stock		Additional paid-in capital	other comprehensive income (loss)	Accumulated deficit		
	Number of shares	Amounts	Shares	Amounts	Amounts		
<b>BALANCE AT JULY 1, 2023</b>	—	\$ —	3,282,479	\$ —	\$ 695,836	\$ —	\$ (678,564) \$ 17,272
<b>CHANGES DURING THE PERIOD:</b>							
Net loss	—	—	—	—	—	—	(6,584) (6,584)
Vesting of restricted stock units, net of withholding tax and shares issued under employee stock purchase plan	—	—	22,302	—	(46)	—	— (46)
Stock-based compensation	—	—	—	—	863	—	— 863
<b>BALANCE AT SEPTEMBER 30, 2023</b>	<b>—</b>	<b>\$ —</b>	<b>3,304,781</b>	<b>\$ —</b>	<b>\$ 696,653</b>	<b>\$ —</b>	<b>\$ (685,148) \$ 11,505</b>
<b>BALANCE AT JULY 1, 2024</b>	<b>—</b>	<b>\$ —</b>	<b>14,536,124</b>	<b>\$ 1</b>	<b>\$ 781,917</b>	<b>\$ (58)</b>	<b>\$ (706,991) \$ 74,869</b>
<b>CHANGES DURING THE PERIOD:</b>							
Net loss	—	—	—	—	—	—	(12,157) (12,157)
Vesting of restricted stock units, net of withholding tax and shares issued under employee stock purchase plan	—	—	2,036	—	(1)	—	— (1)
Stock-based compensation	—	—	—	—	734	—	— 734
Cashless exercise of pre- funded warrants	—	—	213,273	—	—	—	—
Unrealized gains from marketable securities	—	—	—	—	92	—	92
<b>BALANCE AT SEPTEMBER 30, 2024</b>	<b>—</b>	<b>\$ —</b>	<b>14,751,433</b>	<b>\$ 1</b>	<b>\$ 782,650</b>	<b>\$ 34</b>	<b>\$ (719,148) \$ 63,537</b>

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

**VYNE THERAPEUTICS INC.**  
**CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS**  
(U.S. dollars in thousands)  
(Unaudited)

	<b>Nine Months Ended September 30,</b>	
	<b>2024</b>	<b>2023</b>
<b>Cash Flows From Operating Activities:</b>		
Net loss	\$ (27,812)	\$ (22,264)
Adjustments required to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	2,604	2,595
Amortization of premium or discount on marketable securities	(1,899)	—
Changes in operating assets and liabilities:		
Trade receivables, prepaid expenses and other assets and operating lease right-of-use assets	(1,587)	1,017
Trade payables, accrued expenses, employee related obligations and other long-term liabilities	3,812	(1,552)
Operating lease liabilities	(91)	—
Net cash used in operating activities	<u>(24,973)</u>	<u>(20,204)</u>
<b>Cash Flows From Investing Activities:</b>		
Proceeds from the sale of the MST Franchise	—	5,000
Proceeds from sale and maturity of marketable securities	61,100	—
Purchases of marketable securities	(50,473)	—
Net cash provided by investing activities	<u>10,627</u>	<u>5,000</u>
<b>Cash Flows From Financing Activities:</b>		
Proceeds related to issuance of common stock through at-the-market offerings, net of issuance costs	—	156
Redemption of convertible preferred stock	—	(360)
Withholdings from exercise of options and issuance of shares for stock-based compensation arrangements, net	(9)	(65)
Net cash used in financing activities	<u>(9)</u>	<u>(269)</u>
<b>Decrease in cash, cash equivalents and restricted cash</b>	<u>(14,355)</u>	<u>(15,473)</u>
<b>Cash, cash equivalents and restricted cash at beginning of the period</b>	<u>30,674</u>	<u>30,975</u>
<b>Cash, cash equivalents and restricted cash at end of the period</b>	<u><u>\$ 16,319</u></u>	<u><u>\$ 15,502</u></u>
Cash and cash equivalents	16,272	15,448
Restricted cash	47	54
<b>Total cash, cash equivalents and restricted cash</b>	<u><u>\$ 16,319</u></u>	<u><u>\$ 15,502</u></u>
<b>Supplementary information on investing and financing activities not involving cash flows:</b>		
Issuance of vested shares under employee stock purchase plan	\$ 11	\$ 29
Accretion of preferred stock	\$ —	\$ 149

**The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.**

**VYNE Therapeutics Inc.**

**Notes to Unaudited Interim Condensed Consolidated Financial Statements**

**NOTE 1 - NATURE OF OPERATIONS**

VYNE Therapeutics Inc. (the "Company") is a clinical-stage biopharmaceutical company focused on developing differentiated therapies to treat chronic inflammatory and immune-mediated conditions with high unmet need.

In August 2021, the Company entered into a transaction with Tay Therapeutics Limited, formerly known as In4Derm Limited ("Tay"), providing the Company with exclusive worldwide rights to research, develop and commercialize products containing bromodomain and extra-terminal domain ("BET") inhibitors for the treatment of any disease, disorder or condition in humans. Through its access to this library of new chemical BET inhibitor compounds, the Company plans to develop product candidates for a diverse set of indications. Based on data generated to date, the Company has chosen to focus its initial efforts for this platform on select therapeutic areas in immuno-inflammatory disease.

The Company's lead program is VYN201, a locally administered pan- bromodomain ("BD") BET inhibitor designed as a "soft" drug to address diseases involving multiple, diverse inflammatory cell signaling pathways while providing low systemic exposure. In preclinical testing, VYN201 produced consistent reductions in pro-inflammatory and disease-related biomarkers and improvements in disease severity across a variety of inflammatory and fibrotic models. The Company announced positive results from a Phase 1b trial evaluating VYN201 in nonsegmental vitiligo in October 2023 and initiated a Phase 2b trial in nonsegmental vitiligo in June 2024.

The Company's second program is VYN202, an oral small molecule BD2-selective BET inhibitor. VYN202 has been designed to achieve potential class-leading selectivity and potency (BD2 vs. BD1). By maximizing BD2 selectivity, the Company believes VYN202 has the potential to be a more conveniently administered non-biologic treatment option for both acute control and chronic management of immuno-inflammatory indications, where the damaging effects of unrestricted inflammatory signaling activity are common. The Company initiated a Phase 1a single ascending dose/multiple ascending dose ("SAD"/"MAD") trial of VYN202 in June 2024 and announced positive data from the SAD portion of the trial in September 2024.

The Company intends to advance its product candidates through clinical development toward regulatory approval. As part of its strategy to maximize the value of its pipeline, the Company may partner with larger pharmaceutical companies to expand and accelerate the development of its programs and explore therapeutic areas outside of its core focus in immunology.

For additional information regarding the sale of the Company's legacy commercial business (the "MST Franchise") to Journey Medical Corporation ("Journey") in January 2022 and the Company's licensing arrangements with Tay, see "Note 3 - Strategic Agreements."

The Company is a Delaware corporation, has its principal executive offices in Bridgewater, New Jersey and operates as one business segment.

*Reverse stock split and recasting of per-share amounts*

On February 8, 2023, the Company's board of directors approved a 1-for-18 reverse stock split of its outstanding shares of common stock. The reverse stock split was effected on February 10, 2023 at 5:01 p.m. Eastern time. At the effective time, every 18 issued and outstanding shares of the Company's common stock were converted into one share of common stock. No fractional shares were issued in connection with the reverse stock split, and in lieu thereof, each holder of fractional shares was entitled to receive a cash payment (without interest or deduction) from the Company's transfer agent in an amount equal to such holder's respective pro rata share of the total net proceeds from the Company's transfer agent's sale of all fractional shares at the then-prevailing prices on the open market. A proportionate adjustment was also made to the maximum number of shares issuable under the Company's 2019 Equity Incentive Plan, 2018 Omnibus Incentive Plan and 2019 Employee Share Purchase Plan. The number of authorized shares of the Company's common stock and the par value of each share of common stock remained unchanged.

Unless noted, all common stock and per share amounts contained in these unaudited condensed consolidated financial statements have been retroactively adjusted to reflect the 1-for-18 reverse stock split.

#### *Securities Purchase Agreement*

On October 27, 2023, the Company entered into a Securities Purchase Agreement (the "Securities Purchase Agreement") with certain institutional and other accredited investors (collectively, the "Purchasers"), pursuant to which the Company agreed to sell and issue to the Purchasers in a private placement transaction (the "Private Placement") (i) 10,652,543 shares of the Company's common stock and (ii) with respect to certain Purchasers, Pre-Funded Warrants to purchase 28,614,437 shares of common stock in lieu thereof (the "Pre-Funded Warrants"). The purchase price per share of common stock was \$2.245 per share (the "Stock Purchase Price") and the purchase price for the Pre-Funded Warrants was the Stock Purchase Price minus \$0.0001 per Pre-Funded Warrant. On November 1, 2023, the Company received gross proceeds of \$ 88.2 million from the Private Placement, before deducting fees to the placement agent and offering expenses payable by the Company. This transaction resulted in \$5.5 million of issuance costs and net proceeds of \$82.7 million.

#### *Liquidity and Capital Resources*

As of September 30, 2024, the Company had cash, cash equivalents, restricted cash and marketable securities of \$ 70.2 million and an accumulated deficit of \$719.1 million. The Company had no outstanding debt as of September 30, 2024. For the nine months ended September 30, 2024, the Company incurred a net loss of \$27.8 million and used \$25.0 million of cash in operations. Other than in connection with its legacy commercial business that was sold in January 2022, the Company has funded its operations primarily through private and public placements of its equity, debt and warrants and through fees, cost reimbursements and payments received from its licensees. The Company has incurred losses and experienced negative operating cash flows since its inception and anticipates that it will continue to incur losses until such a time when its product candidates, if approved, are commercially successful, if at all. The Company will not generate any revenue from any current or future product candidates unless and until it obtains regulatory approval and commercializes such products.

If the Company's available cash, cash equivalents, restricted cash and marketable securities are insufficient to satisfy its liquidity requirements, the Company may need to raise additional capital to fund its operations. No assurance can be given as to whether additional needed financing will be available on terms acceptable to the Company, if at all. If sufficient funds on acceptable terms are not available when needed, the Company may be required to suspend or forego certain planned activities. Failure to manage discretionary spending or raise additional financing, as needed, would adversely impact the Company's ability to achieve its intended business objectives and have an adverse effect on its results of operations and future prospects. In addition, the amount of proceeds the Company may be able to raise pursuant to its currently effective shelf registration statement on Form S-3 is limited. As of the filing of this Quarterly Report on Form 10-Q, the Company is subject to the general instructions of Form S-3 known as the "baby shelf rules." Under these rules, the amount of funds the Company can raise through primary public offerings of securities in any 12-month period using its registration statement on Form S-3 is limited to one-third of the aggregate market value of the shares of the Company's common stock held by its non-affiliates. Therefore, the Company will be limited in the amount of proceeds it is able to raise by selling shares of common stock using its Form S-3 until such time as the Company's public float exceeds \$75.0 million.

In accordance with Accounting Standards Codification ("ASC") Subtopic 205-40, Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern, the Company has evaluated whether there are conditions and events, considered in the aggregate, that raise substantial doubt about the Company's ability to continue as a going concern within one year after the date that its unaudited interim condensed consolidated financial statements are issued. The Company believes its existing cash, cash equivalents, restricted cash and marketable securities are sufficient to fund its operating and capital expenditure requirements for a period of at least 12 months from the date of issuance of these unaudited interim condensed consolidated financial statements.

#### **NOTE 2 - SIGNIFICANT ACCOUNTING POLICIES**

##### **a. Basis of Presentation**

The unaudited interim condensed consolidated financial statements of the Company have been prepared in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP") for interim financial statements. In the opinion of management, the Company has made all necessary adjustments, which include normal recurring adjustments necessary for a fair statement of the Company's unaudited condensed consolidated financial position, results of operations, cash flow and statement of stockholders' equity for the interim periods presented. Certain information and disclosures normally included in the annual audited consolidated financial statements prepared in accordance with U.S. GAAP have been condensed or omitted. Certain prior period amounts have been reclassified to conform to current year presentation.

These unaudited interim condensed consolidated financial statements should be read in conjunction with the Company's audited consolidated financial statements contained in the Company's Annual Report on Form 10-K for the year ended December 31, 2023, as filed with the SEC on March 1, 2024.

The results for the three and nine months ended September 30, 2024 are not necessarily indicative of the results expected for the year ending December 31, 2024.

**b. Principles of Consolidation**

The unaudited interim condensed consolidated financial statements include the accounts of the Company and its subsidiaries. Intercompany balances and transactions have been eliminated upon consolidation.

**c. Use of Estimates**

The preparation of unaudited condensed consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, and disclosure of contingent assets and liabilities at the date of the unaudited condensed consolidated financial statements and reported amounts of income and expenses during the reporting period. Significant items subject to such estimates and assumptions include research and development accruals. Actual results could differ from the Company's estimates.

**d. Cash and cash equivalents**

The Company considers cash equivalents to be all short-term, highly liquid investments, which include short-term bank deposits, treasury bills and money market funds with original maturities of three months or less from the date of purchase that are not restricted as to withdrawal or use and are readily convertible to known amounts of cash.

**e. Restricted cash**

At both September 30, 2024 and December 31, 2023, the Company had restricted cash of less than \$0.1 million, representing bank guarantees.

**f. Marketable securities**

Marketable securities with original maturities of greater than three months and remaining maturities of less than one year from the balance sheet date are classified as short-term. Marketable securities with remaining maturities of greater than one year from the balance sheet date are classified as long-term.

The Company classifies all marketable securities as available-for-sale debt securities. The Company's marketable securities are measured and reported at fair value using either quoted prices in active markets for identical securities or quoted prices in markets that are not active for identical or similar securities. Unrealized gains and losses are reported as a separate component of stockholders' equity. The cost of securities sold is determined on a specific identification basis, and realized gains and losses, if any, are included in other income, net within the consolidated statement of operations and comprehensive loss.

**g. Revenue Recognition**

The Company accounts for its revenue transactions under the Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") Topic 606, *Revenue from Contracts with Customers*. In accordance with ASC Topic 606, the Company recognizes revenues when its customers obtain control of its product for an amount that reflects the consideration it expects to receive from its customers in exchange for that product. To determine revenue recognition for contracts that are determined to be in scope of ASC Topic 606, the Company performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the Company satisfies the performance obligation. The Company only applies the five-step model to contracts when it is probable that the Company will collect the consideration it is entitled to in exchange for the goods or services it transfers to the customer. Once the contract is determined to be within the scope of ASC Topic 606, the Company assesses the goods or services promised within each contract and determines those that are performance obligations and assesses whether each promised good or service is distinct. The Company then recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when such performance obligation is satisfied.

Following the disposition of the MST Franchise in January 2022, the Company does not have any revenue generating products; however, the Company may receive royalty revenues from the sale of specified products (see "Note 4 - Discontinued Operations").

#### **Royalty Revenues and Collaboration Agreements**

The Company is entitled to royalty payments with respect to sales of Finacea foam. The Company previously licensed the rights to Finacea foam to LEO Pharma A/S ("LEO Pharma"). Finacea foam was not part of the MST Franchise that was sold in January 2022. Royalties are recognized as revenue when the product is sold by Leo Pharma. For both the three months ended September 30, 2024 and 2023, royalty revenues were \$0.1 million. For the nine months ended September 30, 2024 and 2023, royalty revenues were \$0.4 million and \$0.3 million, respectively.

For collaboration agreements under ASC 606, the Company identifies the contract, identifies the performance obligations, determines the transaction price, allocates the contract transaction price to the performance obligations, and recognizes the revenue when (or as) the performance obligation is satisfied.

The Company identifies the performance obligations included within the agreement and evaluates which performance obligations are distinct. Upfront payments for licenses are evaluated to determine if the license is capable of being distinct from the obligations to participate on certain development and/or commercialization committees with the collaboration partners and supply manufactured drug product for clinical trials. For performance obligations that are satisfied over time, the Company utilizes the input method and revenue is recognized by consistently applying a method of measuring progress toward complete satisfaction of that performance obligation. The Company periodically reviews estimated periods of performance based on the progress under each arrangement and accounts for the impact of any changes in estimated periods of performance on a prospective basis.

Milestone payments are a form of variable consideration as the payments are contingent upon achievement of a substantive event. Milestone payments are estimated and are included in the transaction price when the Company determines that it is probable that there will not be a significant reversal of cumulative revenue recognized in future periods.

#### **Product Sales Provisions**

The Company's net product revenues were generated through sales of AMZEEQ, which was approved by the FDA in October 2019 and was commercially launched in the United States in January 2020, and ZILXI, which was approved by the FDA in May 2020 and was commercially launched in the United States in October 2020. The Company sold the MST Franchise on January 12, 2022 and, as such, the Company no longer generates revenue from the sale of these products.

Provisions for distribution fees, trade discounts and chargebacks related to the sales of AMZEEQ and ZILXI are reflected as a reduction to trade receivables, net on the unaudited condensed consolidated balance sheet. All other provisions, including rebates, other discounts and return provisions are reflected as a liability within accrued expenses on the unaudited condensed consolidated balance sheet. The revenue reserve accrual was \$2.2 million and \$2.3 million as of September 30, 2024 and December 31, 2023, respectively. Under the terms of the Asset Purchase Agreement, the Company retained and is responsible for historical liabilities of the commercial business operations based on events occurring prior to the sale other than those liabilities expressly assumed by Journey.

#### **Contract Assets and Contract Liabilities**

The Company did not have any contract assets (unbilled receivables) related to product sales as of September 30, 2024 or December 31, 2023, as customer invoicing generally occurred before or at the time of revenue recognition. Similarly, the Company did not have any contract assets (unbilled receivables) related to its royalty revenues as of September 30, 2024 or December 31, 2023.

The Company did not have any contract liabilities as of September 30, 2024 or December 31, 2023, as the Company did not receive payments in advance of fulfilling its performance obligations to its customers.

#### **h. Collaboration arrangements**

The Company analyzes its collaboration arrangements to assess whether they are within the scope of ASC Topic 808, *Collaborative Arrangements* (ASC 808), to determine whether such arrangements involve joint operating activities performed by parties that are both active participants in the activities and exposed to significant risks and rewards that are dependent on the

commercial success of such activities. To the extent the arrangement is within the scope of ASC 808, the Company will assess whether aspects of the arrangement between it and their collaboration partner are within the scope of other accounting literature.

**i. Research and development expenses**

All expenses associated with research and development are expensed as incurred. Research and development expenses include expenses directly attributable to conducting the Company's research and development programs, including expenses incurred under arrangements with third parties, such as contract research organizations, contract development and manufacturing organizations and consultants as well as the cost of clinical trials, clinical trial supplies, salaries, stock-based compensation expenses, payroll taxes and other employee benefits.

Expenses are considered incurred based on an evaluation of the progress to completion of specific tasks under each contract using information and data provided by the service providers and vendors or the Company's estimate of the level of service that has been performed at each reporting date, whereas payments are dictated by the terms of each agreement, such as the successful enrollment of a certain number of patients, site initiation, and the completion of clinical trial milestones. As such, depending on the timing of payment relative to the receipt of goods or services, management may record prepaid expenses, accrued expenses, or other assets.

The Company makes estimates of accrued research and development expenses as of each balance sheet date in the unaudited condensed consolidated financial statements based on facts and circumstances known at that time. There may also be instances in which payments made to the Company's vendors will exceed the level of services provided and result in a prepayment of the expense. In accruing expenses, the Company estimates the time period over which services will be performed and the level of effort to be expended in each period. If the actual timing of the performance of services by a third party or contract research organization or the level of effort varies from the estimate, the Company adjusts the accrual or the amount of prepaid expenses accordingly. Although the Company does not expect estimates to be materially different from amounts actually incurred, the Company's understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and may result in reporting higher or lower amounts in any particular period. To date, there have not been any material adjustments to the Company's prior estimates of accrued research and development expenses.

**j. Credit losses**

An allowance is maintained for potential credit losses in accordance with accounting standards update ("ASU") No. 2016-13, *Financial Instruments - Credit Losses*. The Company evaluates its allowance based on expected losses rather than incurred losses, which is known as the current expected credit loss ("CECL") model. The allowance is determined using the loss rate approach and is measured on a collective (pool) basis when similar risk characteristics exist. Where financial instruments do not share risk characteristics, they are evaluated on an individual basis. The allowance is based on relevant available information, from internal and external sources, relating to past events, current conditions, and reasonable and supportable forecasts. Trade receivable balances are written off against the allowance when it is deemed probable that the receivable will not be collected. Trade receivables, net are stated net of reserves for certain sales allowances and credit losses. Credit losses were not material for the three and nine months ended September 30, 2024 and 2023.

**k. Fair value measurement**

Fair value is based on the price that would be received from the sale of an asset or that would be paid to transfer a liability in an orderly transaction between market participants at the measurement date. In order to increase consistency and comparability in fair value measurements, the guidance establishes a fair value hierarchy that prioritizes observable and unobservable inputs used to measure fair value into three broad levels, which are described as follows:

- Level 1: Quoted prices (unadjusted) in active markets that are accessible at the measurement date for assets or liabilities. The fair value hierarchy gives the highest priority to Level 1 inputs.
- Level 2: Observable prices that are based on inputs not quoted on active markets but corroborated by market data or active market data of similar or identical assets or liabilities.
- Level 3: Unobservable inputs are used when little or no market data is available. The fair value hierarchy gives the lowest priority to Level 3 inputs.

In determining fair value, the Company utilizes valuation techniques that maximize the use of observable inputs and minimize the use of unobservable inputs to the extent possible and considers counterparty credit risk in its assessment of fair value.

**I. Net loss per share**

Net loss per share, basic and diluted, is computed on the basis of the net loss from continuing operations for the period divided by the weighted average number of shares of common stock outstanding during the period. Diluted net loss per share is based upon the weighted average number of shares of common stock and of common stock equivalents outstanding when dilutive.

The Company has issued the Pre-Funded Warrants, which do not expire until they are exercised in full (see "Note 7 - Mezzanine Equity and Stockholders' Equity"). Pursuant to the guidance of ASC 260-10, the Company concluded that because the equity-classified Pre-Funded Warrants were immediately exercisable for little or no cash consideration, due to the non-substantive exercise price, all of the necessary conditions for issuance of the underlying shares of common stock had been met when the Pre-Funded Warrants were issued. Therefore, the underlying shares of common stock should be included in the denominator for both the calculation of basic and diluted net loss per share of common stock for the three and nine months ended September 30, 2024.

The following stock options, restricted stock units ("RSUs") and warrants were excluded from the calculation of diluted net loss per share because their effect would have been anti-dilutive for the periods presented (data presented as number of shares):

	<b>September 30,</b>	
	<b>2024</b>	<b>2023</b>
Outstanding stock options and RSUs	2,378,566	240,401
Warrants	27,509	27,509

**m. Concentration of credit risks**

Financial instruments that potentially subject the Company to concentration of credit risk consist principally of cash and cash equivalents, restricted cash, marketable securities and accounts receivable. The Company deposits cash and cash equivalents with highly rated financial institutions and, as a matter of policy, limits the amounts of credit exposure to any single financial institution. In addition, all marketable securities carry a high credit rating or are government insured. The Company has not experienced any material credit losses in these accounts and does not believe it is exposed to significant credit risk on these instruments.

Existing royalty receivables relate to one customer, but do not present a credit risk due to their immaterial nature. Restricted cash as of September 30, 2024 was less than \$0.1 million, which does not present a credit risk due to its immaterial nature.

**n. Employee Retention Tax Credit**

In March 2020, the Coronavirus Aid, Relief, and Economic Security Act (the "CARES Act") was signed into law, providing numerous tax provisions and other stimulus measures, including employee retention tax credits ("ERTC"). The ERTC was a refundable tax credit against certain employment taxes for qualifying businesses retaining employees on their payroll during the COVID-19 pandemic and allowed eligible employers to claim a refundable tax credit against the employer share of Social Security tax equal to 70% of the qualified wages they paid to employees, initially from March 27, 2020 until June 30, 2021, and extended through September 30, 2021. During 2022, the Company filed returns with the Internal Revenue Service (IRS) and claimed credits totaling \$1.3 million. During the first quarter of 2023, the Company received the full \$ 1.3 million. As there is no authoritative guidance under U.S. GAAP on accounting for government assistance to for-profit business entities, the Company has accounted for the ERTC by analogy to International Accounting Standard, Accounting for Government Grants and Disclosure of Government Assistance ("IAS 20"). The ERTC filings remain open to examination by the IRS until April 2025, and as such the Company has recorded the \$1.3 million received within other current liabilities on the unaudited condensed consolidated balance sheet as of September 30, 2024 until such a time that the Company has reasonable assurance that the conditions associated with the grants have been met.

**o. Warrants**

The Company accounts for warrants as either equity-classified or liability-classified instruments based on an assessment of the warrant's specific terms and applicable authoritative guidance in ASC Topic 480, *Distinguishing Liabilities from Equity* ("ASC 480") and ASC Topic 815, *Derivatives and Hedging* ("ASC 815"). The assessment considers whether the warrants are freestanding financial instruments pursuant to ASC 480, meet the definition of a liability pursuant to ASC 480, and meet all of the requirements for equity classification under ASC 815, including whether the warrants are indexed to the Company's own common stock, among other conditions for equity classification. This assessment, which requires the use of professional judgment, is conducted at the time of warrant issuance and as of each subsequent reporting period end date while the warrants

are outstanding. For issued warrants that meet all of the criteria for equity classification, the warrants are required to be recorded as a component of additional paid-in capital at the time of issuance. For issued warrants that do not meet all the criteria for equity classification, the warrants are required to be recorded at their initial fair value on the date of issuance, and each balance sheet date thereafter. Changes in the estimated fair value of the warrants are recognized as a non-cash gain or loss on the statements of operations. Liability-classified warrants are required to be accounted for at fair value both on the date of issuance and on subsequent accounting period ending dates, with all changes in fair value after the issuance date recorded as a component of other income, net in the statements of operations. As of September 30, 2024 and December 31, 2023, all of the Company's outstanding warrants were equity-classified warrants.

**p. Newly issued and recently adopted accounting pronouncements**

*Recent Accounting Guidance Issued:*

In June 2016, the FASB issued Accounting Standard Update No. 2016-13, " *Financial Instruments - Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments*" (ASU 2016-13), which requires companies to measure credit losses of financial instruments, including customer accounts receivable and marketable securities, utilizing a methodology that reflects expected credit losses and requires consideration of a broader range of reasonable and supportable information to inform credit loss estimates. Subsequent to the issuance of ASU 2016-13, the FASB issued several additional Accounting Standard Updates to clarify implementation guidance, provide narrow-scope improvements and provide additional disclosure guidance. As a smaller reporting company, the Company adopted ASU 2016-13 as of January 1, 2023, and there was no material impact on the unaudited condensed consolidated financial statements upon adoption.

In December 2022, the FASB issued Accounting Standards Update No. 2022-06, " *Reference Rate Reform (Topic 848): Deferral of the Sunset Date of Topic 848*" (ASU 2022-06), which provides extension of the sunset date of Topic 848 from December 31, 2022 to December 31, 2024. The Company is currently evaluating the impact of ASU 2020-04 and ASU 2022-06 on its unaudited condensed consolidated financial statements. Currently, the Company does not expect the adoption of the new standard to have a material impact on the unaudited condensed consolidated financial statements.

In November 2023, the FASB issued ASU No. 2023-07, " *Segment Reporting (Topic 280)—Improvements to Reportable Segment Disclosures*" (ASU 2023-07), to improve reportable segment disclosure requirements, primarily through enhanced disclosures about significant segment expenses. The amendments are effective for fiscal years beginning after December 15, 2023 and interim periods within fiscal years beginning after December 15, 2024. Early adoption is permitted. The Company is evaluating the impact the adoption of this guidance will have on its unaudited condensed consolidated financial statements and related disclosures.

In December 2023, the FASB issued ASU No. 2023-09, " *Income Taxes (Topic 740)—Improvements to Income Tax Disclosures*" (ASU 2023-09), which is intended to enhance the transparency and decision usefulness of income tax disclosures. Public business entities are required to adopt this standard for annual fiscal periods beginning after December 15, 2024 and early adoption is permitted. The Company is evaluating the impact the adoption of this guidance will have on its unaudited condensed consolidated financial statements and related disclosures.

## NOTE 3 - STRATEGIC AGREEMENTS

### ***Agreements with Tay Therapeutics***

#### *Evaluation and Option Agreement*

In April 2021, the Company entered into an Evaluation and Option Agreement (the "Option Agreement") with Tay. Pursuant to the Option Agreement, Tay granted the Company an exclusive option to obtain certain exclusive worldwide rights to research, develop and commercialize products containing Tay's BET inhibitor compounds for the treatment of any disease, disorder or condition in humans. Pursuant to the Option Agreement, the Company agreed to use commercially reasonable efforts to stabilize, develop and manufacture a product with a pan-BD BET inhibitor as its active ingredient and Tay agreed to provide a mutually agreed data package and select new chemical entity development candidate from its highly selective BET inhibitor compounds (the "Oral BETi Compounds"). The Company paid a \$1.0 million non-refundable cash payment to Tay upon execution of the Option Agreement, 50% of which was to be used by Tay in the development of the Oral BETi Compounds.

Under the terms of the Option Agreement, the Company's option (the "Oral Option") with respect to the Oral BETi Compounds was to expire on June 30, 2022 (the "Option Term"), but in June 2022, the Company and Tay entered into a Letter Agreement (the "Letter Agreement") to extend the Option Term to February 28, 2023. Pursuant to the terms of the Letter Agreement, the Company paid Tay \$386,366 (£300,000) on June 28, 2022 to extend the Option Term. In addition, on August 29, 2022, the Company made a second payment of \$997,407 (£850,000) pursuant to the terms of the Letter Agreement following the discovery of potential Oral BETi Compounds for further development. Both payments were recorded as research and development expense. On February 27, 2023, the parties entered into an additional Letter Agreement (the "Second Letter Agreement") pursuant to which the Option Term was extended to April 30, 2023. As consideration for the extension of the Option Term, the Company paid Tay \$ 250,000 upon the execution of the Second Letter Agreement. Per the terms of the Second Letter Agreement, this fee was deducted from the upfront fee paid by the Company to Tay following the Company's exercise of the Oral Option, as described below.

#### *License for Locally Administered Pan-BD BET Inhibitor Program (VYN201)*

On August 6, 2021, the Company exercised its option with respect to the VYN201 program and, on August 9, 2021, the parties entered into a License Agreement (the "VYN201 License Agreement") granting the Company a worldwide, exclusive license that is sublicensable through multiple tiers to exploit certain of Tay's pan-BD BET inhibitor compounds in all fields. The Company has the sole responsibility for development, regulatory, marketing and commercialization activities to be conducted for the licensed products at its sole cost and discretion. The Company is required to use commercially reasonable efforts to develop and, if approved, commercialize such products. Pursuant to the VYN201 License Agreement, a joint development committee consisting of one representative from each party reviews the progress of the development plan for the licensed products. Pursuant to the VYN201 License Agreement, the Company may develop a product that contains or incorporates a specific BET inhibitor, whether alone or in combination with other active ingredients, in any form, formulation, presentation, or dosage, and for any mode of administration.

The Company made a \$0.5 million cash payment to Tay in connection with entering into the VYN201 License Agreement. Pursuant to the VYN201 License Agreement, the Company has agreed to make cash payments to Tay of up to \$15.75 million upon the achievement of specified clinical development and regulatory approval milestones with respect to each licensed topical product in the United States for all indications, of which \$1.8 million has been paid or accrued through September 30, 2024. Tay is entitled to additional milestone payments upon the achievement of regulatory approvals in certain non-U.S. jurisdictions. In addition, with respect to any products the Company commercializes under the VYN201 License Agreement, the Company will pay tiered royalties to Tay on net sales of such licensed products by the Company, its affiliates, or sublicensees, of 5%, 7.5% and 10% based on tiered annual net sales bands subject to specified reductions. The Company is obligated to pay royalties until the latest of (1) the tenth anniversary of the first commercial sale of the relevant licensed product, (2) the expiration of the last valid claim of the licensed patent rights covering such licensed product in such country and (3) the expiration of regulatory exclusivity for the relevant licensed product in the relevant country, on a licensed product-by-licensed product and country-by-country basis.

#### *License for Selective BET Inhibitor Program (VYN202)*

On April 28, 2023, the Company exercised the Oral Option and entered into a license agreement (the "VYN202 License Agreement") with Tay granting the Company a worldwide, exclusive license that is sublicensable through multiple tiers to exploit certain of Tay's Oral BETi Compounds in all fields. The Company has the sole responsibility for development, regulatory, marketing and commercialization activities to be conducted for the licensed products at the sole cost and discretion

of the Company, and shall use commercially reasonable efforts to develop and, if approved, commercialize such products. VYNE may sublicense its rights to a third party without Tay's consent. Pursuant to the License Agreement, a joint development committee consisting of one representative from each party reviews the progress of the development plan for the licensed products.

The Company made a cash payment of \$3.75 million, after deducting the \$250,000 paid in February 2023, to Tay in connection with entering into the VYN202 License Agreement. This payment was recorded as a research and development expense in the period paid. Pursuant to the terms of the VYN202 License Agreement, the Company agreed to make cash payments to Tay of up to \$43.75 million upon the achievement of specified clinical development and regulatory approval milestones with respect to each licensed oral product in the United States for all indications, of which \$1.3 million has been paid or accrued through September 30, 2024. Tay is entitled to additional milestone payments upon the achievement of regulatory approvals in certain non-U.S. jurisdictions. In addition, with respect to any products the Company commercializes under the VYN202 License Agreement, the Company will pay tiered royalties to Tay on net sales of such licensed products by the Company, its affiliates, or sublicensees, of 5%, 7.5% and 10% based on tiered annual net sales bands subject to specified reductions. The Company is obligated to pay royalties until the latest of (1) the tenth anniversary of the first commercial sale of the relevant licensed product, (2) the expiration of the last valid claim of the licensed patent rights covering such licensed product in such country and (3) the expiration of regulatory exclusivity for the relevant licensed product in the relevant country, on a licensed product-by-licensed product and country-by-country basis.

#### ***Sale of the MST Franchise***

On January 12, 2022, VYNE entered into an Asset Purchase Agreement (the "Purchase Agreement") with Journey pursuant to which the Company sold its MST Franchise to Journey. The assets include certain contracts, including the license agreement with Cutia Therapeutics (HK) Limited ("Cutia"), inventory and intellectual property related to the MST Franchise (together, the "Assets"). Pursuant to the Agreement, Journey assumed certain liabilities of the MST Franchise. There were no current or long-term liabilities recorded by the Company which were transferred to Journey.

Pursuant to the Purchase Agreement, the Company received an upfront payment of \$ 20.0 million at the closing of the sale of the MST franchise and received an additional \$5.0 million deferred payment in January 2023. The Company is also eligible to receive sales milestone payments of up to \$ 450.0 million in the aggregate upon the achievement of specified levels of net sales on a product-by-product basis, beginning with annual net sales exceeding \$100.0 million (with products covered in three categories (1) AMZEEQ (and certain modifications), (2) ZILXI (and certain modifications), and (3) FCD105 and other products covered by the patents being transferred, including certain modifications). In addition, the Company is entitled to receive certain payments from any licensing or sublicensing of the assets by Journey outside of the United States.

#### **NOTE 4 – DISCONTINUED OPERATIONS**

The Company determined that the sale of the MST Franchise represented a strategic shift that had a major effect on the business and therefore the MST Franchise met the criteria for classification as discontinued operations. Accordingly, the MST Franchise is reported as discontinued operations in accordance with ASC 205-20, *Discontinued Operations*. In accordance with ASC 205-20, only expenses specifically identifiable and related to a business to be disposed may be presented in discontinued operations. As such, the research and development, marketing, and general and administrative expenses in discontinued operations include corporate costs incurred directly to solely support the MST Franchise. The negative product sales for the three and nine months ended September 30, 2023 were primarily attributable to a change in the product returns provision following the sale of the MST Franchise.

The following table presents the combined results of discontinued operations of the MST Franchise:

(in thousands)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
	\$ —	\$ (498)	\$ —	\$ (498)
<b>Operating expenses:</b>				
General and administrative	—	15	19	46
<b>Total operating expenses</b>	<b>—</b>	<b>15</b>	<b>19</b>	<b>46</b>
Loss from discontinued operations, before taxes	—	(513)	(19)	(544)
Income tax expense	—	—	—	—
<b>Net loss from discontinued operations</b>	<b>\$ —</b>	<b>\$ (513)</b>	<b>\$ (19)</b>	<b>\$ (544)</b>

There were no non-cash items related to discontinued operations for the nine months ended September 30, 2024 and 2023.

The milestone payments for sales of ZILXI, AMZEEQ and FCD105 represent contingent consideration. Contingent consideration has been accounted for as a gain contingency in accordance with ASC 450, *Contingencies*, and will be recognized in earnings in the period when realizable.

#### NOTE 5 – FAIR VALUE MEASUREMENTS

The Company's financial assets that are measured at fair value as of September 30, 2024 and December 31, 2023 are classified in the tables below in one of the three categories described in "Fair value measurement (k)" in "Note 2 - Significant Accounting Policies" above:

(in thousands)	September 30, 2024			
	Level 1	Level 2	Level 3	Total
Cash and cash equivalents	\$ 11,339	\$ 4,933	\$ —	\$ 16,272
Marketable securities	—	53,913	—	53,913
<b>Total assets</b>	<b>\$ 11,339</b>	<b>\$ 58,846</b>	<b>\$ —</b>	<b>\$ 70,185</b>
 <b>December 31, 2023</b>				
(in thousands)	Level 1	Level 2	Level 3	Total
	\$ 20,353	\$ 10,267	\$ —	\$ 30,620
Marketable securities	—	62,633	—	62,633
<b>Total assets</b>	<b>\$ 20,353</b>	<b>\$ 72,900</b>	<b>\$ —</b>	<b>\$ 93,253</b>

Other financial instruments consist of trade receivables, trade payables and accrued expenses. The fair value of these financial instruments approximates their carrying value due to their short-term nature. In determining the fair value of its Level 2 investments, the Company relied on quoted prices for identical securities in markets that are not active. These quoted prices were obtained by the Company with the assistance of a third-party pricing service based on available trade, bid and other observable market data for identical securities.

#### NOTE 6 – MARKETABLE SECURITIES

As of September 30, 2024 and December 31, 2023, marketable securities consisted of U.S. Government and agency bonds as well as U.S. Treasury bills.

The following table sets forth the Company's marketable securities:

(in thousands)	September 30,		December 31,	
	2024		2023	
	U.S. Government and agency debt securities	\$ 23,333	U.S. Treasury bills	\$ 31,886
Total	\$ 53,913	\$ 30,580	\$ 30,747	\$ 62,633

As of September 30, 2024 and December 31, 2023, the amortized cost, gross unrealized gains, gross unrealized losses and fair value were as follows:

(in thousands)	September 30, 2024			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
	U.S. Government and agency debt securities	\$ 23,323	\$ 12	\$ (2)
U.S. Treasury bills	\$ 30,557	23	—	\$ 30,580
Total	\$ 53,880	\$ 35	\$ (2)	\$ 53,913

  

(in thousands)	December 31, 2023			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
	U.S. Government and agency debt securities	\$ 31,866	\$ 30	\$ (10)
U.S. Treasury bills	\$ 30,742	5	—	\$ 30,747
Total	\$ 62,608	\$ 35	\$ (10)	\$ 62,633

As of September 30, 2024 and December 31, 2023, \$ 53.9 million and \$62.6 million, respectively, of the marketable securities were in an unrealized gain position. The Company determined that unrealized gains and losses on marketable securities were primarily due to interest rate changes. No allowance for credit losses related to any of these securities was recorded for the periods ended September 30, 2024 and December 31, 2023. All maturities are less than 12 months.

#### **NOTE 7 – MEZZANINE EQUITY AND STOCKHOLDERS' EQUITY**

##### **Preferred stock**

As of September 30, 2024, the Company's Amended and Restated Certificate of Incorporation (as amended, the "Certificate of Incorporation") authorized the Company to issue 20,000,000 shares of preferred stock, par value \$ 0.0001 per share. There were no shares of preferred stock issued and outstanding as of September 30, 2024 and December 31, 2023.

Shares of preferred stock may be issued from time to time in one or more series. The voting powers (if any), preferences and relative, participating, optional or other special rights, and the qualifications, limitations and restrictions of any series of preferred stock will be set forth in a Certificate of Designation filed pursuant to the Delaware General Corporation Law, as determined by the Company's Board of Directors.

On November 11, 2022, the Company entered into a Securities Purchase Agreement (the "Purchase Agreement") with Mutual Fund Series Trust, on behalf of AlphaCentric LifeSci Healthcare Fund ("AlphaCentric"), pursuant to which the Company issued on November 14, 2022, in a private placement transaction, an aggregate of 3,000 shares of Series A Convertible Preferred Stock, par value \$ 0.0001 per share (the "Series A Preferred"), for an aggregate subscription amount equal to \$300,000. This transaction resulted in \$ 89,000 of issuance costs and net proceeds of \$ 211,000.

The Company determined that the Series A Preferred should be classified as Mezzanine Equity (temporary equity outside of permanent equity) because the Series A Preferred more closely aligned with debt as the intent was for redemption by either the holder or the Company due to the favorable redemption terms.

The Purchase Agreement required that the Company convene a meeting of its stockholders for the purpose of presenting a proposal (the "Proposal") authorizing the Company's board of directors to approve a reverse stock split of its outstanding

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common stock, with the recommendation of the board of directors that the Proposal be approved, and that the Company use reasonable best efforts to obtain approval of the Proposal. The meeting was convened on January 12, 2023, and the Proposal was approved.

Additionally, the Purchase Agreement contained customary representations, warranties and agreements of the Company and AlphaCentric, and customary indemnification rights and obligations of the parties.

Pursuant to the Purchase Agreement, the Company filed a Certificate of Designation of Preferences, Rights and Limitations of Series A Convertible Preferred Stock (the "Certificate of Designation") with the Secretary of State of Delaware on November 14, 2022 designating 3,000 shares out of the authorized but unissued shares of its preferred stock as Series A Preferred with a par value of \$0.0001 per share and establishing the rights, preferences and limitations of the Series A Preferred. The Certificate of Designation provided, among other things, that except as otherwise provided in the Certificate of Designation or as otherwise required by law, the Series A Preferred would have no voting rights (other than the right to vote as a class on certain matters as provided in the Certificate of Designation). However, pursuant to the Certificate of Designation, each share of Series A Preferred entitled the holder thereof (i) to vote on the Proposal and any proposal to adjourn any meeting of stockholders called for the purpose of voting on the Proposal, and (ii) to 1,000,000 votes per share of Series A Preferred on the Proposal and any such adjournment proposal. The Series A Preferred should, except as required by law, vote together with the common stock (and other issued and outstanding shares of preferred stock entitled to vote), as a single class; provided, however, that such shares of Series A Preferred should, to the extent cast on the Proposal or any such adjournment proposal, be automatically and without further action of the holders thereof voted in the same proportion as the shares of common stock (excluding abstentions and any shares of common stock that are not voted) and any other issued and outstanding shares of preferred stock of the Company entitled to vote (other than the Series A Preferred or shares of such other preferred stock, if any, not voted) are voted on the Proposal. In addition, the Series A Preferred were entitled to customary dividends and distributions when and if paid on shares of the common stock and were entitled to the voting rights discussed above. The Series A Preferred had preference over the common stock with respect to distribution of assets or available proceeds, as applicable, in the event of any voluntary or involuntary liquidation, dissolution or winding up of the Company or any other deemed liquidation event.

The shares of Series A Preferred were convertible at the option of the holder, at a conversion price of \$ 4.68 per share (as adjusted for the reverse stock split), into shares of the Company's common stock, at any time and from time to time from and after 15 business days following the earlier of (i) the date of the approval of the Proposal or (ii) the date the Company otherwise satisfies the Nasdaq listing requirements.

The Company had the right to redeem the Series A Preferred at any time during the 15 business days following the approval of the Proposal (the "Company Redemption Period") at 120% of the stated value. Each holder of Series A Preferred had the right to require the Company to redeem all or a portion of the Series A Preferred held by such holder following the expiration of the Company Redemption Period at 130% of the stated value. In addition, the Company would automatically redeem all of the Series A Preferred within five business days following a delisting event as specified in the Certificate of Designation at 130% of the stated value.

On January 17, 2023, the Company redeemed all outstanding shares of its Series A Preferred, for an aggregate of \$ 360,000 paid to AlphaCentric. The redemption payment represented 120% of the stated value of the Series A Preferred Stock pursuant to the Certificate of Designation.

On January 17, 2023, the Company filed a Certificate of Elimination (the "Certificate") with the Secretary of State of the State of Delaware with respect to the Series A Preferred Stock. The Certificate (i) eliminated the previous designation of 3,000 shares of Series A Preferred Stock from the Company's Amended and Restated Certificate of Incorporation, none of which were outstanding at the time of filing, and (ii) caused such shares of Series A Preferred Stock to resume their status as authorized but unissued and non-designated shares of preferred stock.

### **Common stock**

Pursuant to the Certificate of Incorporation, the Company is authorized to issue 150,000,000 shares of common stock, par value \$ 0.0001 per share. Each share of common stock is entitled to one vote. The holders of common stock are also entitled to receive dividends whenever funds are legally available and when and if declared by the board of directors, subject to the prior rights of holders of all classes of preferred stock outstanding. The Company has never declared any dividends on common stock.

On February 8, 2023, the Company's Board of Directors approved a 1-for-18 reverse stock split of the Company's outstanding shares of common stock. The reverse stock split was effected on February 10, 2023. At the effective time, every 18 issued and outstanding shares of the Company's common stock were converted into one share of common stock. No fractional shares were issued in connection with the reverse stock split, and in lieu thereof, each holder of fractional shares was entitled to receive a cash payment (without interest or deduction) in an amount equal to such holder's respective pro rata share of the total net proceeds from the Company's transfer agent's sale of all fractional shares at the then-prevailing prices on the open market. The

number of authorized shares of the Company's common stock and the par value of each share of common stock remained unchanged.

Unless noted, all common stock and per share amounts contained in these unaudited condensed consolidated financial statements have been retroactively adjusted to reflect the 1-for-18 reverse stock split.

#### ***Issuances of common stock***

##### *At-the-Market Equity Offering Program*

On August 12, 2021, the Company entered into a sales agreement (the "Cantor Sales Agreement") with Cantor Fitzgerald to sell shares of the Company's common stock, from time to time, with aggregate gross sales proceeds of up to \$50.0 million through an at-the-market equity offering program under which Cantor Fitzgerald would act as the Company's sales agent. Cantor Fitzgerald was entitled to compensation for its services equal to up to 3.0% of the gross proceeds of any shares of common stock sold under the Cantor Sales Agreement. During the nine months ended September 30, 2023, the Company issued and sold 34,589 shares of common stock at a weighted average per share price of \$ 4.52 pursuant to the Cantor Sales Agreement for \$0.2 million in net proceeds. On February 27, 2024, the Company delivered notice to Cantor Fitzgerald to terminate the Cantor Sales Agreement. The Company cannot make any future sales of its common stock pursuant to the Cantor Sales Agreement.

On March 1, 2024, the Company entered into a sales agreement (the "Cowen Sales Agreement") with Cowen and Company, LLC as sales agent ("Cowen") under which the Company may offer and sell, from time to time at its sole discretion, shares of the Company's common stock through Cowen in an at-the-market offering having an aggregate offering price up to \$50.0 million. Cowen is entitled to compensation for its services equal to 3.0% of the gross proceeds of any shares of common stock sold under the Cowen Sales Agreement. The Company did not sell any shares of common stock under the Cowen Sales Agreement during the nine months ended September 30, 2024.

##### *Private Placement*

On October 27, 2023, the Company entered into a Securities Purchase Agreement, pursuant to which the Company agreed to sell and issue to the Purchasers in a Private Placement (i) 10,652,543 shares of the Company's common stock and (ii) with respect to certain Purchasers, Pre-Funded Warrants to purchase 28,614,437 shares of common stock in lieu thereof. The Stock Purchase Price was \$ 2.245 per share and the purchase price for the Pre-Funded Warrants was the Stock Purchase Price minus \$0.0001 per Pre-Funded Warrant. On November 1, 2023, the Company received gross proceeds of \$88.2 million from the Private Placement, before deducting fees to the placement agent and offering expenses payable by the Company. This transaction resulted in \$5.5 million of issuance costs and net proceeds of \$82.7 million.

##### *Pre-Funded Warrants*

The Pre-Funded Warrants issued in the Private Placement will not expire until exercised in full. The Pre-Funded Warrants may not be exercised if the aggregate number of shares of common stock beneficially owned by the holder thereof immediately following such exercise would exceed a specified beneficial ownership limitation; provided, however, that a holder may increase or decrease the beneficial ownership limitation by giving 60 days' notice to the Company, but not to exceed any percentage in excess of 19.99%.

As of December 31, 2023, 131,843 of Pre-Funded Warrants were exercised pursuant to a net exercise mechanism. During the nine months ended September 30, 2024, 639,854 of Pre-Funded Warrants were exercised pursuant to a net exercise mechanism. As of September 30, 2024, 27,842,740 Pre-Funded Warrants remained outstanding.

##### *Other Warrants*

As of September 30, 2024 and December 31, 2023, the Company had warrants to purchase an aggregate of 27,509 shares of the Company's common stock outstanding, with an exercise price of \$8.40, and an expiration date of July 29, 2026. These warrants were issued by Foamix (as defined below) in connection with a financing in July 2019 and were subsequently assumed by the Company in connection with the Merger (as defined below). Pursuant to the warrant certificate, the exercise price of the warrant will be proportionally adjusted in the event that the Company issues common stock at a price per share less than the exercise price (the "Down Round Feature"). In the event that the Down Round Feature is triggered, the Company must calculate the difference between the warrants' fair value, using the Black-Scholes-Merton option-pricing model, before and after the Down Round Feature was triggered using the original exercise price and the new exercise price. The exercise price will be adjusted in the event the Company issues additional shares of common stock below the then-current exercise price, in accordance with the terms of the warrants.

The Pre-Funded Warrants and warrants are classified as a component of permanent equity because they are freestanding financial instruments that are legally detachable and separately exercisable from the shares of common stock with which they were issued, are immediately exercisable, do not embody an obligation for the Company to repurchase its shares, and permit the holders to receive a fixed number of shares of common stock upon exercise. In addition, the Pre-Funded Warrants and warrants do not provide any guarantee of value or return.

#### **NOTE 8 – STOCK-BASED COMPENSATION**

##### *2023 Equity Incentive Plan:*

The Company maintains the 2023 Equity Incentive Plan (the "2023 Plan") and previously maintained the 2019 Equity Incentive Plan (the "2019 Plan") and 2018 Omnibus Incentive Plan (the "2018 Plan"). Following stockholder approval in December 2023, any shares then available for future grant under the 2019 Plan and 2018 Plan were allocated to the 2023 Plan. As of September 30, 2024, 80,795 shares remained issuable under the 2023 Plan, and no further grants will be made under the 2018 Plan or 2019 Plan.

##### *2024 Inducement Plan:*

On February 28, 2024, the Board approved the Company's 2024 Inducement Plan (the "Inducement Plan"). Pursuant to the Inducement Plan and Nasdaq Listing Rule 5635(c)(4), the Company is permitted to grant equity awards as an inducement material to an individual's entering into employment with the Company, subject to certain conditions ("Inducement Grants"). As of September 30, 2024, there were 370,000 shares available for future Inducement Grants.

##### *2019 Employee Share Purchase Plan:*

The Company has adopted an Employee Share Purchase Plan ("ESPP") pursuant to which qualified employees (as defined in the ESPP) may elect to purchase designated shares of the Company's common stock at a price equal to 85% of the lesser of the fair market value of the common stock at the beginning or end of each semi-annual share purchase period ("Purchase Period"). Employees are permitted to purchase the number of shares purchasable with up to 15% of the earnings paid (as such term is defined in the ESPP) to each of the participating employees during the Purchase Period, subject to certain limitations under Section 423 of the U.S. Internal Revenue Code.

As of September 30, 2024, 95,917 shares remained available for grant under the ESPP.

There were 5,285 shares of common stock purchased by employees pursuant to the ESPP during the nine months ended September 30, 2024, and 8,339 shares of common stock purchased by employees pursuant to the ESPP during the nine months ended September 30, 2023.

##### Options and Restricted Stock Units ("RSUs") granted to employees and directors:

For the nine months ended September 30, 2024, the Company granted options and RSUs to employees and directors as follows:

	Nine Months Ended September 30, 2024			
	Award amount in shares	Exercise price range	Vesting period	Expiration
Options	750,000	\$1.96 - \$2.33	1 year - 4 years	10 years
RSUs	435,000	—	4 years	—

During the nine months ended September 30, 2024, the fair value of options and RSUs granted to employees and directors was \$ 2.4 million.

There were no options or RSUs granted to employees and directors for the nine months ended September 30, 2023.

The fair value of RSUs granted is based on the share price on the grant date. One share of common stock will be issued upon settlement of each RSU that vests.

The fair value of each option granted is estimated using the Black-Scholes option pricing method. The volatility is based on a combination of historical volatilities of companies in comparable stages as well as companies in the industry, by statistical analysis of daily share pricing model. The risk-free interest rate assumption is based on observed interest rates appropriate for the expected term of the options granted in dollar terms. The Company's management uses the expected term of each option as its expected life. The expected term of the options granted represents the period of time that granted options are expected to remain outstanding and is based on the simplified method. Under the simplified method, the expected life of an option is presumed to be the midpoint between the vesting date and the end of the contractual term. The Company used the simplified method due to the lack of sufficient historical exercise data to provide a reasonable basis upon which to otherwise estimate the expected life of the stock options.

The underlying data used for computing the fair value of the options are as follows:

	Nine Months Ended September 30,
	2024
Fair value of common stock	\$1.64 - \$1.94
Dividend yield	— %
Expected volatility	104.63% - 105.73%
Risk-free interest rate	3.95% - 4.28%
Expected term	6 years

#### Stock-based compensation expenses:

The following table illustrates the effect of stock-based compensation on the line items on the unaudited condensed consolidated statements of operations:

(in thousands)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Research and development expenses	\$ 127	\$ 207	\$ 423	\$ 399
General and administrative	607	656	2,181	2,196
<b>Total</b>	<b>\$ 734</b>	<b>\$ 863</b>	<b>\$ 2,604</b>	<b>\$ 2,595</b>

#### **NOTE 9 – COMMITMENTS AND CONTINGENCIES**

##### **Litigation and contingencies**

The Company may periodically become subject to legal proceedings and claims arising in connection with its business. As of September 30, 2024, there were no claims or actions pending against the Company that, in the opinion of management, are likely to have a material adverse effect on the Company.

**Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations.**

*You should read the following discussion and analysis of our financial condition and results of operations in conjunction with the unaudited condensed consolidated financial statements and the notes thereto included elsewhere in this Quarterly Report on Form 10-Q for the period ended September 30, 2024 and our audited financial statements and notes thereto included in our Annual Report on Form 10-K for the year ended December 31, 2023. In this Quarterly Report on Form 10-Q, unless otherwise indicated, all references to the "Company," "we," "us" and "our" or similar terms refer to VYNE Therapeutics Inc.*

**Company Overview**

We are a clinical-stage biopharmaceutical company focused on developing differentiated therapies to treat chronic inflammatory and immune-mediated conditions with high unmet need. Our unique and proprietary BET inhibitors, which comprise our InhiBET™ platform, are designed to overcome limitations of early generation BET inhibitors by leveraging alternative routes of administration and enhanced selectivity.

In August 2021, we entered into a transaction with Tay providing us with exclusive worldwide rights to research, develop and commercialize products containing BET inhibitors for the treatment of any disease, disorder or condition in humans. Through our access to this library of new chemical BET inhibitor compounds, we plan to develop product candidates for a diverse set of indications. Based on data generated to date, we have chosen to focus our initial efforts for this platform on select therapeutic areas in immuno-inflammatory disease.

Our lead program is VYN201, a locally administered pan-BD BET inhibitor designed as a "soft" drug to address diseases involving multiple, diverse inflammatory cell signaling pathways while providing low systemic exposure. In preclinical testing, VYN201 produced consistent reductions in pro-inflammatory and disease-related biomarkers and improvements in disease severity across a variety of inflammatory and fibrotic models. In November 2022, we initiated a Phase 1 clinical trial evaluating a topical formulation of VYN201 for the treatment of nonsegmental vitiligo. In the first quarter of 2023, we announced positive preliminary safety and tolerability, pharmacokinetic and hematology data from the Phase 1a portion of the trial. The first nonsegmental vitiligo patient was dosed in the Phase 1b portion of the trial in January 2023, and on October 30, 2023, we announced positive data from the Phase 1b trial, in which significant clinical improvement in F-VASI was observed in the 1% and 2% dose cohorts after 16 weeks of treatment. We initiated a Phase 2b trial of VYN201 in June 2024. The Phase 2b trial in subjects with nonsegmental vitiligo is a randomized, double-blind, vehicle-controlled trial evaluating the efficacy, safety and pharmacokinetics of once-daily VYN201 gel in three dose cohorts (1%, 2% and 3% concentrations) compared to vehicle for 24 weeks, followed by a 28-week active treatment extension. We expect to enroll approximately 40 to 50 patients in each arm and to report top-line results from the 24-week double-blind portion of the trial in mid-2025.

Our second program is VYN202, an oral small molecule BD2-selective BET inhibitor. VYN202 has been designed to achieve potential class-leading selectivity and potency (BD2 vs. BD1). By maximizing BD2 selectivity, we believe VYN202 has the potential to be a more conveniently administered non-biologic treatment option for both acute control and chronic management of immuno-inflammatory indications, in which the damaging effects of unrestricted inflammatory signaling activity are common. We initiated a Phase 1a single ascending dose/multiple ascending dose ("SAD/MAD") trial of VYN202 in June 2024 and announced positive data from the SAD portion of the trial in September 2024. We expect to report top-line results from the MAD portion of the trial in the fourth quarter of 2024. If the Phase 1a trial is successfully completed, we plan to initiate Phase 1b trials in adult subjects with moderate-to-severe plaque psoriasis and moderate-to-severe adult-onset rheumatoid arthritis, with top-line results anticipated in the second half of 2025.

We intend to advance our product candidates through clinical development toward regulatory approval. As part of our strategy to maximize the value of our pipeline, we may partner with larger pharmaceutical companies to expand and accelerate the development of our programs and explore therapeutic areas outside of our core focus in immunology.

**Financial Overview**

We have incurred net losses since our inception. Except from the period from 2020 to 2022, when we conducted commercial operations, our business activities have been primarily limited to developing product candidates, raising capital and performing research and development activities. As of September 30, 2024, we had an accumulated deficit of \$719.1 million. We recorded net losses of \$27.8 million and \$22.3 million for the nine months ended September 30, 2024 and 2023, respectively.

Currently, our resources are focused on our immuno-inflammatory pipeline. Research and development activities for these programs, including preclinical and clinical testing of our product candidates, will require significant additional financing. Our future viability is dependent on our ability to successfully execute our business strategy and develop our product candidates and raise additional capital to finance operations. Our failure to raise capital as and when needed could have a negative impact on our financial condition and ability to pursue our business strategies.

## **Business and Macroeconomic Conditions**

Uncertainty in the global economy presents significant risks to our business. We are subject to continuing risks and uncertainties in connection with the current macroeconomic environment, including inflation, interest rates, financial market volatility and uncertainty, the impact of war or military conflict, including the wars in Ukraine and the Middle East, rising tensions between China and Taiwan and the response thereto, the potential impact of the proposed BIOSECURE Act, public health pandemics and supply chain disruptions. Adverse effects of these large macroeconomic conditions have been prevalent in many of the areas where we, our contract research organizations, suppliers or third-party business partners conduct business and as a result, we have experienced disruptions and may continue to experience more pronounced disruptions in our operations. In addition, financial markets have experienced a period of high volatility due to these macroeconomic factors. The persistence of this volatility may impact our ability to engage in capital market activities and adequately fund our operations. As of the filing date of this Quarterly Report on Form 10-Q, the extent to which these macroeconomic events and conditions may impact our financial condition, results of operations or liquidity is uncertain. The effect of these macroeconomic events and conditions may not be fully reflected in our results of operations and overall financial performance until future periods. For further discussion of the potential impacts of macroeconomic events on our business, financial condition, and operating results, see the section of our most recent Annual Report on Form 10-K captioned "Risk Factors."

## **Development and License Agreements**

### ***Agreements with Tay***

#### ***License for Locally Administered Pan-BD BET Inhibitor Program (VYN201)***

In August 2021, we exercised our option with respect to the VYN201 program and entered into a license agreement (the "VYN201 License Agreement") granting us a worldwide, exclusive license that is sublicensable through multiple tiers to exploit certain of Tay's pan-BD BET inhibitor compounds in all fields. We have the sole responsibility for development, regulatory, marketing and commercialization activities to be conducted for the licensed products at our sole cost and discretion.

We are required to use commercially reasonable efforts to develop and, if approved, commercialize such products. Pursuant to the VYN201 License Agreement, a joint development committee consisting of one representative from each party reviews the progress of the development plan for the licensed products. Pursuant to the VYN201 License Agreement, we may develop a product that contains or incorporates a specific BET inhibitor, whether alone or in combination with other active ingredients, in any form, formulation, presentation, or dosage, and for any mode of administration.

We made a \$0.5 million cash payment to Tay in 2021 in connection with entering into the VYN201 License Agreement. Pursuant to the VYN201 License Agreement, we agreed to make cash payments to Tay of up to \$15.75 million upon the achievement of specified clinical development and regulatory approval milestones with respect to each licensed topical product in the United States for all indications, of which \$1.8 million has been paid or accrued through September 30, 2024. Tay is entitled to additional milestone payments upon the achievement of regulatory approvals in certain non-U.S. jurisdictions. In addition, with respect to any products we commercialize under the VYN201 License Agreement, we will pay tiered royalties to Tay on net sales of such licensed products by us, our affiliates, or sublicensees, of 5%, 7.5% and 10% based on tiered annual net sales bands subject to specified reductions. We are obligated to pay royalties until the latest of (1) the tenth anniversary of the first commercial sale of the relevant licensed product, (2) the expiration of the last valid claim of the licensed patent rights covering such licensed product in such country and (3) the expiration of regulatory exclusivity for the relevant licensed product in the relevant country, on a licensed product-by-licensed product and country-by-country basis.

#### ***License for Selective BET Inhibitor Program (VYN202)***

On April 28, 2023, we exercised the Oral Option and entered into a license agreement (the "VYN202 License Agreement" and together with the VYN201 License Agreement, the "Tay License Agreements") with Tay granting us a worldwide, exclusive license that is sublicensable through multiple tiers to exploit certain of Tay's Oral BETi Compounds in all fields. We have the sole responsibility for development, regulatory, marketing and commercialization activities to be conducted for the licensed products at our sole cost and discretion, and shall use commercially reasonable efforts to develop and, if approved, commercialize such products. We may sublicense our rights to a third party without Tay's consent.

We made a cash payment of \$3.75 million to Tay in connection with entering into the VYN202 License Agreement. Pursuant to the terms of the VYN202 License Agreement, we agreed to make cash payments to Tay of up to \$43.75 million upon the achievement of specified clinical development and regulatory approval milestones with respect to each licensed oral product in the United States for all indications, of which \$1.3 million has been paid or accrued through September 30, 2024. Tay is entitled to additional milestone payments upon the achievement of regulatory approvals in certain non-U.S. jurisdictions. In addition,

with respect to any products we commercialize under the VYN202 License Agreement, we will pay tiered royalties to Tay on net sales of such licensed products by us, our affiliates, or sublicensees, of 5%, 7.5% and 10% based on tiered annual net sales bands subject to specified reductions. We are obligated to pay royalties until the latest of (1) the tenth anniversary of the first commercial sale of the relevant licensed product, (2) the expiration of the last valid claim of the licensed patent rights covering such licensed product in such country and (3) the expiration of regulatory exclusivity for the relevant licensed product in the relevant country, on a licensed product-by-licensed product and country-by-country basis.

## **Components of Operating Results**

### **Revenues**

Historically, we have generated revenues under development and license agreements, including royalty payments from sales of Finacea foam. We previously licensed the rights to Finacea to LEO Pharma A/S ("LEO Pharma"). This license was not part of the sale of our commercial business to Journey. For both the three months ended September 30, 2024 and 2023, royalty revenues from LEO Pharma in connection with sales of Finacea were \$0.1 million. For the nine months ended September 30, 2024 and 2023, royalty revenues from LEO Pharma in connection with sales of Finacea were \$0.4 million and \$0.3 million, respectively.

### **Operating Expenses**

#### *Research and Development Expenses*

Our research and development expenses primarily relate to the development of VYN201 and VYN202. We charge all research and development expenses to operations as they are incurred.

Our total research and development expenses for the three months ended September 30, 2024 and 2023 were \$10.2 million and \$3.3 million, respectively. Total research and development expenses for the nine months ended September 30, 2024 and 2023 were \$21.3 million and \$13.3 million, respectively.

Research and development expenses consist primarily of:

- employee-related expenses, including salaries, benefits and related expenses, including stock-based compensation expenses, for research and development personnel;
- expenses incurred under agreements with third parties, including contract research organizations, subcontractors, suppliers and consultants that conduct regulatory activities, clinical trials and preclinical studies;
- expenses incurred to acquire, develop and manufacture clinical trial materials;
- expenses incurred under licensing agreements;
- costs associated with the creation, development and protection of intellectual property; and
- other costs associated with preclinical and clinical activities and regulatory operations.

#### *General and Administrative Expenses*

Our general and administrative expenses for both the three months ended September 30, 2024 and 2023 were \$3.0 million. Total general and administrative expenses for the nine months ended September 30, 2024 and 2023 were \$10.0 million and \$9.5 million, respectively.

Our general and administrative expenses consist principally of:

- employee-related expenses, including salaries, benefits and related expenses, including stock-based compensation expenses;
- professional fees for legal, auditing, tax and other consulting expenses; and
- facility, insurance, information technology and travel expenses.

**Other Income, net**

Other income, net primarily consists of interest earned on our cash, cash equivalents and marketable securities.

**Income Taxes and Net Operating Loss Carryforwards**

We have incurred significant net operating losses ("NOLs") since our inception. We expect to continue to incur NOLs until such a time when we generate adequate revenues for us to reach profitability. As of December 31, 2023, we had federal and state net operating loss carryforwards of \$331.1 million and \$41.7 million, respectively, of which \$44.3 million will begin to expire in 2031 for federal and \$21.3 million will begin to expire in 2040 for state purposes. As of December 31, 2023, we had federal research and development tax credit carryforwards of \$6.9 million, which will begin to expire in 2031. We have no state research and development tax credit carryforwards. As of December 31, 2023, we had \$307.2 million in federal and state NOLs with no limited period of use. There were no significant updates through September 30, 2024.

NOLs and tax credit carryforwards are subject to review and possible adjustment by the Internal Revenue Service and may become subject to an annual limitation in the event of certain cumulative changes in the ownership interest of significant stockholders over a three-year period in excess of 50%, as defined under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended. This could limit the amount of tax attributes that can be utilized annually to offset future taxable income or tax liabilities. The amount of the annual limitation is determined based on the value of our company immediately prior to the ownership change. Subsequent ownership changes may further affect the limitation in future years. State NOLs and tax credit carryforwards may be subject to similar limitations under state laws. We have not completed a Section 382 study through September 30, 2024; however, we may have experienced ownership changes in the past, including in connection with the 2020 merger between Menlo Therapeutics (our predecessor company) and Foamix Pharmaceuticals Ltd. Our private placement transaction in November 2023 also likely resulted in an ownership change for purposes of Section 382. We may experience ownership changes in the future as a result of the subsequent shifts in our stock ownership, some of which may be outside of our control. As a result, even if we earn net taxable income, our ability to use the NOL and tax credit carryforwards may be materially limited, which could harm our future operating results by effectively increasing our future tax obligations.

**Results of Operations**

**Comparison of the Three Months Ended September 30, 2024 and 2023**

(in thousands, except %)	Three Months Ended September 30,		Increase/(Decrease)	Increase/(Decrease)	
	2024	2023		\$	%
<b>Revenues</b>					
Royalty revenues	\$ 121	\$ 114	\$ 7	6.1	%
<b>Total revenues</b>	<b>121</b>	<b>114</b>	<b>7</b>	<b>6.1</b>	<b>%</b>
<b>Operating expenses:</b>					
Research and development	10,248	3,318	6,930	208.9	%
General and administrative	2,964	3,030	(66)	(2.2)	%
<b>Total operating expenses</b>	<b>13,212</b>	<b>6,348</b>	<b>6,864</b>	<b>108.1</b>	<b>%</b>
<b>Operating loss</b>	<b>(13,091)</b>	<b>(6,234)</b>	<b>6,857</b>	<b>110.0</b>	<b>%</b>
Other income, net	934	163	771	*	
<b>Loss from continuing operations before income taxes</b>	<b>(12,157)</b>	<b>(6,071)</b>	<b>6,086</b>	<b>100.2</b>	<b>%</b>
Income tax expense	—	—	—	—	%
<b>Loss from continuing operations</b>	<b>(12,157)</b>	<b>(6,071)</b>	<b>6,086</b>	<b>100.2</b>	<b>%</b>
Loss from discontinued operations, net of income taxes	—	(513)	(513)	(100.0)	%
<b>Net loss</b>	<b>\$ (12,157)</b>	<b>\$ (6,584)</b>	<b>\$ 5,573</b>	<b>84.6</b>	<b>%</b>

\* Percentage not meaningful.

**Revenues**

Revenues totaled \$0.1 million for both the three months ended September 30, 2024 and 2023, consisting of royalty revenue from our royalty agreement with LEO Pharma.

**Research and Development Expenses**

Our research and development expenses for the three months ended September 30, 2024 were \$10.2 million, representing an increase of \$6.9 million, or 208.9%, compared to \$3.3 million for the three months ended September 30, 2023. The increase was primarily driven by increased expenses associated with our ongoing Phase 2b trial of VYN201 in subjects with nonsegmental vitiligo and our ongoing Phase 1a SAD/MAD trial of VYN202 of \$5.0 million and \$1.7 million, respectively. Both trials were initiated in June 2024. In addition, employee-related expenses increased by \$0.3 million following the hiring of additional research and development personnel.

**General and Administrative Expenses**

Our general and administrative expenses for both the three months ended September 30, 2024 and 2023 were approximately \$3.0 million, representing an immaterial change year-over-year.

**Other Income, Net**

Other income, net for the three months ended September 30, 2024 and 2023 was \$0.9 million and \$0.2 million, respectively, and was related to interest income earned on cash, cash equivalents and marketable securities.

**Loss from Discontinued Operations, Net of Income Taxes**

Due to the sale of the MST Franchise during the first quarter of 2022, in accordance with ASC 205, Discontinued Operations, we have classified the results of the MST Franchise as discontinued operations in our consolidated statements of operations for all periods presented. See "Note 4 - Discontinued Operations" in the accompanying unaudited interim condensed consolidated financial statements.

**Comparison of the Nine Months Ended September 30, 2024 and 2023**

(in thousands, except %)	Nine Months Ended September 30,		Increase/(Decrease)	Increase/(Decrease)	
	2024	2023		\$	%
<b>Revenues</b>					
Royalty revenues	\$ 417	\$ 348	\$ 69		19.8 %
<b>Total revenues</b>	<b>417</b>	<b>348</b>	<b>69</b>		<b>19.8 %</b>
<b>Operating expenses:</b>					
Research and development	21,262	13,284	7,978	60.1	%
General and administrative	10,022	9,490	532	5.6	%
<b>Total operating expenses</b>	<b>31,284</b>	<b>22,774</b>	<b>8,510</b>		<b>37.4 %</b>
<b>Operating loss</b>	<b>(30,867)</b>	<b>(22,426)</b>	<b>8,441</b>		<b>37.6 %</b>
Other income, net	3,074	706	2,368		*
<b>Loss from continuing operations before income taxes</b>	<b>(27,793)</b>	<b>(21,720)</b>	<b>6,073</b>		<b>28.0 %</b>
Income tax expense	—	—	—	—	%
<b>Loss from continuing operations</b>	<b>(27,793)</b>	<b>(21,720)</b>	<b>6,073</b>		<b>28.0 %</b>
Loss from discontinued operations, net of income taxes	(19)	(544)	(525)		(96.5) %
<b>Net loss</b>	<b>\$ (27,812)</b>	<b>\$ (22,264)</b>	<b>\$ 5,548</b>		<b>24.9 %</b>

**Revenues**

Revenues totaled \$0.4 million and \$0.3 million for the nine months ended September 30, 2024 and 2023, respectively, consisting of royalty revenue from our royalty agreement with LEO Pharma.

**Research and Development Expenses**

Our research and development expenses for the nine months ended September 30, 2024 were \$21.3 million, representing an increase of \$8.0 million, or 60.1%, compared to \$13.3 million for the nine months ended September 30, 2023. The increase was primarily driven by expenses associated with preparatory and clinical trial activities for a Phase 2b trial of VYN201 in subjects with nonsegmental vitiligo, which was initiated in June 2024, of \$8.5 million, which included a \$1.0 million milestone payment due to Tay. Additionally, employee-related expenses increased by \$0.7 million following the hiring of additional research and development personnel. These increases were partially offset by a decrease in expenses associated with VYN202 of \$1.2 million, primarily driven by lower amounts owed to Tay under the VYN202 License Agreement, partially offset by an increase in clinical trial expenses. During the nine months ended September 30, 2023, we made cash payments to Tay totaling \$4.0 million in connection with entering into the VYN202 License Agreement. We incurred a \$1.0 million development milestone payment due to Tay following the initiation of a Phase 1a SAD/MAD trial of VYN202 in June 2024.

**General and Administrative Expenses**

Our general and administrative expenses for the nine months ended September 30, 2024 were \$10.0 million, representing an increase of \$0.5 million, or 5.6%, compared to \$9.5 million for the nine months ended September 30, 2023. The increase was primarily related to \$0.4 million of consulting and professional fees and \$0.1 million of employee-related expenses.

**Other Income, Net**

Other income, net for the nine months ended September 30, 2024 and 2023 was \$3.1 million and \$0.7 million, respectively, and was related to interest income earned on cash, cash equivalents and marketable securities.

**Loss from Discontinued Operations, Net of Income Taxes**

Due to the sale of the MST Franchise during the first quarter of 2022, in accordance with ASC 205, Discontinued Operations, we have classified the results of the MST Franchise as discontinued operations in our consolidated statements of operations for

all periods presented. See "Note 4 - Discontinued Operations" in the accompanying unaudited interim condensed consolidated financial statements.

## Liquidity and Capital Resources

### ***Sources of Liquidity***

Since the sale of the MST Franchise in January 2022, we have not generated any revenue from product sales. In addition, we have incurred losses and experienced negative operating cash flows since our inception and anticipate that we will continue to incur losses until such a time when our product candidates, if approved, are commercially successful, if at all. We will not generate any revenue from any current or future product candidates unless and until we obtain regulatory approval and commercialize such products. As a result, we will need additional capital to fund our operations, which we may obtain from additional equity or debt financings, collaborations, licensing arrangements or other sources. See the section titled "Risk Factors" in our most recent Annual Report on Form 10-K for additional risks associated with our substantial capital requirements.

As of September 30, 2024, we had cash, cash equivalents, restricted cash and marketable securities of \$70.2 million and an accumulated deficit of \$719.1 million. We had no outstanding debt as of September 30, 2024. For the nine months ended September 30, 2024, we incurred a net loss of \$27.8 million and used \$25.0 million of cash in operations. Based on our current operating plan, we believe our existing cash, cash equivalents, restricted cash and marketable securities are sufficient to fund our operating and capital expenditure requirements for a period of at least 12 months from the date of issuance of the unaudited interim condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q.

Our sources of funding for both the nine months ended September 30, 2024 and 2023 are further evaluated in the cash flow section below. Other than our obligations pursuant to the Tay License Agreements, we have no ongoing material financial commitments that may affect our liquidity over the next five years. See the section titled "Development and License Agreements—Agreements with Tay" for additional discussion of our financial obligations under the Tay License Agreements.

### ***Future Funding Requirements***

We do not expect to generate any product revenue unless and until we obtain regulatory approval of and commercialize any of our product candidates, and we do not know when, or if, that will occur. Until we can generate significant revenue from product sales, if ever, we will continue to require substantial additional capital to develop our current and future product candidates and fund operations for the foreseeable future. We expect our expenses to increase substantially in connection with our ongoing activities, particularly as we advance the preclinical activities and studies and initiate clinical trials. We are subject to all the risks incident in the development of new biopharmaceutical products, and we may encounter unforeseen expenses, difficulties, complications, delays, and other unknown factors that may harm our business.

In order to complete the development of VYN201 and VYN202 (including making milestone payments pursuant to the VYN201 License Agreement and VYN202 License Agreement), or any future product candidates, we will require substantial additional capital. Accordingly, we expect to seek to raise any necessary additional capital through private or public equity or debt financings, loans or other capital sources, which could include income from collaborations, partnerships or other marketing, distribution, licensing or other strategic arrangements with third parties, or from grants. To the extent that we raise additional capital through equity financings or convertible debt securities, the ownership interest of our stockholders will be or could be diluted, and the terms of these securities may include liquidation, voting or other preferences that adversely affect the rights of our common stockholders. Debt financing and equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, including restricting our operations and limiting our ability to incur liens, issue additional debt, pay dividends, repurchase our common stock, make certain investments or engage in merger, consolidation, licensing, or asset sale transactions. If we raise capital through collaborations, partnerships, and other similar arrangements with third parties, we may be required to grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves. We may be unable to raise additional capital from these sources on favorable terms, or at all.

In addition, the amount of proceeds we may be able to raise pursuant to our currently effective shelf registration statement on Form S-3 is limited. As of the filing of this Quarterly Report on Form 10-Q, we are subject to the general instructions of Form S-3 known as the "baby shelf rules." Under these rules, the amount of funds we can raise through primary public offerings of securities in any 12-month period using our registration statement on Form S-3 is limited to one-third of the aggregate market value of the shares of our common stock held by our non-affiliates. Therefore, we will be limited in the amount of proceeds we

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are able to raise by selling shares of common stock using our Form S-3 until such time as our public float exceeds \$75.0 million.

Our ability to raise additional capital may also be adversely impacted by global economic conditions and disruptions to, and volatility in, the credit and financial markets in the United States and worldwide resulting from bank failures, other general macroeconomic conditions and otherwise. The failure to obtain sufficient capital on acceptable terms when needed could have a material adverse effect on our business, results of operations or financial condition, including requiring us to delay, reduce or curtail our research or product development efforts. We cannot provide assurance that we will ever generate positive cash flow from operating activities.

Our present and future funding requirements will depend on many factors, including the following:

- the scope, timing, progress, results, and costs of researching and developing VYN201 and VYN202 and conducting clinical trials, including larger and later-stage trials;
- the scope, timing, progress, results, and costs of preclinical studies and clinical trials for any other current and future programs;
- the time and costs involved in obtaining regulatory approval for our other pipeline product candidates and any delays we may encounter as a result of evolving regulatory requirements or adverse results with respect to any of these product candidates;
- terms and timing of any acquisitions, collaborations or other arrangements;
- the cost and timing of attracting, hiring, and retaining skilled personnel to support our operations;
- the number of potential new products we identify and decide to develop;
- the costs involved in filing and prosecuting patent applications and obtaining, maintaining and enforcing patents or defending against claims or infringements raised by third parties, and license royalties or other amounts we may be required to pay to obtain rights to third party intellectual property rights; and
- the costs associated with operating as a public company.

A change in the outcome of any of these or other factors with respect to the development of any of our product candidates could significantly change the costs and timing associated with the development of that product candidate. In addition, we based projections of operating capital requirements on our current operating plan, which includes several assumptions that may prove to be incorrect, and we may use all of our available capital resources sooner than we expect.

**Cash Flows**

The following table summarizes our cash flows for the nine months ended September 30, 2024 and 2023:

(in thousands)	<b>Nine Months Ended September 30,</b>	
	<b>2024</b>	<b>2023</b>
<b>Net cash (used in) / provided by:</b>		
Operating activities	\$ (24,973)	\$ (20,204)
Investing activities	\$ 10,627	\$ 5,000
Financing activities	\$ (9)	\$ (269)

*Net Cash Used in Operating Activities*

During the nine months ended September 30, 2024, net cash used in operating activities was \$25.0 million and primarily reflected our net loss of \$27.8 million adjusted for non-cash stock-based compensation expense of \$2.6 million, partially offset by the amortization of premium on marketable securities of \$1.9 million. The remainder of the cash used in operations was driven by changes in operating assets and liabilities.

During the nine months ended September 30, 2023, net cash used in operating activities was \$20.2 million and primarily reflected our net loss of \$22.3 million adjusted for the \$2.6 million of non-cash stock-based compensation expense. The remainder of the cash used in operations was driven by changes in operating assets and liabilities.

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### *Net Cash Provided by Investing Activities*

During the nine months ended September 30, 2024, net cash provided by investing activities was \$10.6 million and consisted of \$61.1 million of proceeds received from the sale and maturity of marketable securities, partially offset by \$50.5 million paid for the purchase of marketable securities.

During the nine months ended September 30, 2023, net cash provided by investing activities of \$5.0 million consisted of the deferred payment received from Journey in January 2023.

### *Net Cash Used in Financing Activities*

During the nine months ended September 30, 2024, net cash used in financing activities was immaterial.

During the nine months ended September 30, 2023, net cash used in financing activities was \$0.3 million and consisted of \$0.4 million paid for the redemption of convertible preferred stock, partially offset by \$0.2 million of proceeds received from the issuance of common stock under our at-the-market equity facility.

### **Critical Accounting Policies, Significant Judgments and Use of Estimates**

Our unaudited interim condensed consolidated financial statements have been prepared in accordance with U.S. generally accepted accounting principles ("GAAP"). The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported expenses incurred during the reporting periods. Our estimates are based on our historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. We believe that the accounting policies discussed below are critical to understanding our historical and future performance, as these policies relate to the more significant areas involving management's judgments and estimates.

Our critical accounting policies are described in our Annual Report on Form 10-K for the year ended December 31, 2023 filed with the SEC on March 1, 2024. There have been no material changes to these policies for the nine months ended September 30, 2024, except as set forth below.

Effective June 30, 2024, product revenue, net, product returns, and discontinued operations were no longer deemed critical accounting policies and research and development expenses was newly identified as a critical accounting policy.

### **Research and Development Expenses**

All expenses associated with research and development are expensed as incurred. Research and development expenses include expenses directly attributable to the conduct of our research and development programs, including expenses incurred under arrangements with third parties, such as contract research organizations, contract development and manufacturing organizations and consultants as well as salaries, stock-based compensation expenses, payroll taxes and other employee benefits.

Expenses are considered incurred based on an evaluation of the progress to completion of specific tasks under each contract using information and data provided by the service providers and vendors or our estimate of the level of service that has been performed at each reporting date, whereas payments are dictated by the terms of each agreement, such as the successful enrollment of a certain number of patients, site initiation, and the completion of clinical trial milestones. As such, depending on the timing of payment relative to the receipt of goods or services, management may record either prepaid expenses or accrued services.

We make estimates of our accrued research and development expenses as of each balance sheet date in our unaudited condensed consolidated financial statements based on facts and circumstances known to us at that time. There may also be instances in which payments made to our vendors will exceed the level of services provided and result in a prepayment of the expense. In accruing expenses, we estimate the time period over which services will be performed and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from the estimate, we adjust the accrual or the amount of prepaid expenses accordingly. Although we do not expect our estimates to be materially different from amounts actually incurred, our understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and may result in reporting higher or lower amounts in any particular period. To date, there have not been any material adjustments to our prior estimates of accrued research and development expenses.

## **Off-Balance Sheet Arrangements**

We are not party to any off-balance sheet arrangements that have, or are reasonably likely to have, a material current or future effect on our financial condition, revenues or expenses, results of operations, liquidity, capital expenditures or capital resources.

## **Recently Issued and Adopted Accounting Pronouncements**

See "Newly issued and recently adopted accounting pronouncements (p)" in "Note 2 - Significant Accounting Policies" in the Notes to Unaudited Interim Condensed Consolidated Financial Statements for a discussion of recently adopted accounting pronouncements and accounting pronouncements not yet adopted, and their expected impact on our financial position and results of operations.

## **Item 3. Quantitative and Qualitative Disclosures about Market Risk.**

We are a smaller reporting company as defined by Rule 12b-2 of the Exchange Act and Item 10 of Regulation S-K. As such, we are not required to provide the information set forth in this item.

## **Item 4. Controls and Procedures.**

### **Evaluation of Disclosure Controls and Procedures**

We maintain "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to the company's management, including its chief executive officer and chief financial officer, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

Our management, with the participation of our Chief Executive Officer and our Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures (as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act and regulations promulgated thereunder) as of September 30, 2024. Based on such evaluation, those officers have concluded that, as of September 30, 2024, our disclosure controls and procedures were effective at the reasonable assurance level.

### **Changes in Internal Control over Financial Reporting**

There were no changes in our internal control over financial reporting that occurred during the three months ended September 30, 2024 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

## **Part II. OTHER INFORMATION**

### **Item 1. Legal Proceedings.**

From time to time, we may become involved in litigation or other legal proceedings relating to claims that we consider to be arising in the ordinary course of our business. There are currently no claims or actions pending against us that, in the opinion of our management, are likely to have a material adverse effect on our business.

### **Item 1A. Risk Factors.**

Information about our risk factors is contained in Part I, Item 1A of our Annual Report on Form 10-K for the fiscal year ended December 31, 2023 filed with the SEC on March 1, 2024. As of the date of the issuance of these condensed consolidated financial statements, there have been no material changes in our risk factors from those disclosed in the Annual Report.

### **Item 2. Unregistered Sales of Equity Securities and Use of Proceeds.**

During the three months ended September 30, 2024, we issued an aggregate of 213,273 shares of common stock upon the exercise of Pre-Funded Warrants pursuant to a net exercise mechanism. Each Pre-Funded Warrant had an exercise price of \$0.0001 per share. The issuances of the shares of common stock were exempt from registration under the Securities Act of 1933, as amended, pursuant to Section 3(a)(9) thereof as an exchange with an existing security holder where no commission or other remuneration is paid or given for soliciting such exchange.

### **Item 3. Defaults Upon Senior Securities.**

None.

### **Item 4. Mine Safety Disclosures.**

Not applicable.

### **Item 5. Other Information.**

#### Adoption, Modification and Termination of Rule 10b5-1 Plans and Certain Other Trading Arrangements

During the three months ended September 30, 2024, none of our directors and officers (as defined in Rule 16a-1(f) under the Securities Exchange Act of 1934, as amended) adopted or terminated any contracts, instructions or written plans for the purchase or sale of our securities.

#### Inducement Plan Amendment

As of November 6, 2024, 131,907 shares remained available for issuance under the 2023 Plan. In addition, the Board reduced the number of shares available to be issued under the Inducement Plan to one share.

**Item 6. Exhibits.**

The following documents are filed, or furnished as applicable, as part of this Quarterly Report on Form 10-Q:

Exhibit Number	Exhibit Description	Exhibit Index			Filed Herewith
		Form	Date	Number	
3.1(a)	<a href="#">Amended and Restated Certificate of Incorporation.</a>	10-K	3/17/2022	3.1	
3.1(b)	<a href="#">Certificate of Designation of Preferences, Rights, and Limitations of Series A Convertible Preferred Stock.</a>	10-Q	11/14/2022	3.1(b)	
3.1(c)	<a href="#">Certificate of Elimination</a>	8-K	1/17/2023	3.1	
3.1(d)	<a href="#">Certificate of Amendment to the Amended and Restated Certificate of Incorporation.</a>	8-K	2/10/2023	3.1	
3.2	<a href="#">Amended and Restated Bylaws.</a>	10-Q	11/14/2022	3.2	
31.1	<a href="#">Certification of the Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.</a>				X
31.2	<a href="#">Certification of the Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.</a>				X
32.1*	<a href="#">Certification of the Chief Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.</a>				X
32.2*	<a href="#">Certification of the Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.</a>				X
101.INS	XBRL Instance Document - the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document.				X
101.SCH	XBRL Taxonomy Extension Schema Document with Embedded Linkbase Documents.				X
104	The cover page of VYNE Therapeutics Inc.'s Quarterly Report on Form 10-Q for the quarter ended September 30, 2024, formatted in Inline XBRL (included within Exhibit 101 attachments).				

\* The certifications attached as Exhibit 32.1 and Exhibit 32.2 that accompany this Quarterly Report on Form 10-Q are not deemed filed with the Securities and Exchange Commission and are not to be incorporated by reference into any filing of VYNE Therapeutics Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date of this Quarterly Report on Form 10-Q, irrespective of any general incorporation language contained in such filing.

**Signatures**

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Dated: November 7, 2024

**VYNE Therapeutics Inc.**

By: /s/ David Domzalski  
David Domzalski  
*Chief Executive Officer*  
(*On Behalf of the Registrant and as Principal Executive Officer*)

By: /s/ Tyler Zeronda  
Tyler Zeronda  
*Chief Financial Officer*  
(*Principal Financial Officer and Principal Accounting Officer*)

**CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER**

I, David Domzalski, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of VYNE Therapeutics Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 7, 2024

By: \_\_\_\_\_ /s/ David Domzalski  
\_\_\_\_\_  
David Domzalski  
Principal Executive Officer

**CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER**

I, Tyler Zeronda, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of VYNE Therapeutics Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 7, 2024

By: /s/ Tyler Zeronda  
Tyler Zeronda  
Principal Financial Officer

**CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER PURSUANT TO  
18 U.S.C. SECTION 1350,  
AS ADOPTED PURSUANT TO  
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Quarterly Report on Form 10-Q of VYNE Therapeutics Inc. (the "Company"), for the quarterly period ended September 30, 2024 as filed with the Securities and Exchange Commission (the "Report"), I, David Domzalski, President and Chief Executive Officer and principal executive officer, hereby certify as of the date hereof, solely for purposes of 18 U.S.C. §1350, as adopted pursuant to §906 of the Sarbanes-Oxley Act of 2002, that to the best of my knowledge:

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 7, 2024

By: /s/ David Domzalski  
David Domzalski  
Chief Executive Officer

This certification accompanies the Report pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 and shall not, except to the extent required by the Sarbanes-Oxley Act of 2002, be deemed filed by the Company for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and is not incorporated by reference into any filing of the Company.

**CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER PURSUANT TO  
18 U.S.C. SECTION 1350,  
AS ADOPTED PURSUANT TO  
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Quarterly Report on Form 10-Q of VYNE Therapeutics Inc. (the "Company"), for the quarterly period ended September 30, 2024 as filed with the Securities and Exchange Commission (the "Report"), I, Tyler Zeronda, Chief Financial Officer, Treasurer and principal financial officer, hereby certify as of the date hereof, solely for purposes of 18 U.S.C. §1350, as adopted pursuant to §906 of the Sarbanes-Oxley Act of 2002, that to the best of my knowledge:

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 7, 2024

By: /s/ Tyler Zeronda  
Tyler Zeronda  
Principal Financial Officer

This certification accompanies the Report pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 and shall not, except to the extent required by the Sarbanes-Oxley Act of 2002, be deemed filed by the Company for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and is not incorporated by reference into any filing of the Company.